

BALLOON EXPANSION DRUG DELIVERY CATHETER AND STENT DEPLOYMENT DRUG DELIVERY CATHETER IN RAPID EXCHANGE CONFIGURATION

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Abstract of JP 11178929 (A)

PROBLEM TO BE SOLVED: To achieve quick and easy progress and withdrawal of a catheter.

SOLUTION: This catheter is equipped with a catheter shaft 401 and an expansion catheter 412. The expansion balloon 412 has an outer layer 430 which has plural openings 428 (for releasing a drug) and an inner layer. The catheter shaft 401 is equipped with a first lumen 407, a second lumen 405 communicated with the inner layer, and a third lumen 406 to house a guide wire 418. The third lumen 406 has a first opening at the tip end 419 and a second opening 417. Thereby the guide wire 428 is placed in the catheter shaft 401 only in between the first opening and the second opening 417. A stent 440 and deployment means thereof are equipped on the tip end part of the catheter shaft 401.



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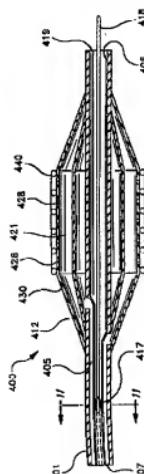
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(54)【発明の名称】迅速交換構成のバルーン膨張型薬剤撒送用カテーテルおよびステント配置型薬剤撒送用カテーテル

(57)【要約】

【課題】迅速かつ容易なカテーテルの前進および引抜を達成すること。

【解決手段】カテーテルシャフト401と、膨張バルーン412と、を具備してなるカテーテルであって、膨張バルーン412が、外層430および内層を有し、外層430は、(薬剤放出のため)複数の開口428を有し、カテーテルシャフト401は、外層430に連通した第1管腔407と、内層に連通した第2管腔405と、ガイドワイヤ418を収容する第3管腔406と、を備え、第3管腔406は、先端419において開口する第1開口と第2開口417とを有し、これにより、ガイドワイヤ418が、第1開口と第2開口417との間においてのみカテーテルシャフト401内に配置されており、カテーテルシャフト401の先端部には、ステント440とその配置手段とが設けられている。



【特許請求の範囲】

【請求項1】 ステント配置型薬剤搬送用カテーテルであって、先端、該先端の近傍に位置する少なくとも1つの薬剤搬送用ポート(130)、および、該薬剤搬送用ポート(130)に対して薬剤を供給するための少なくとも1つの薬剤搬送用管腔(114)を備えた第1カテーテルシャフトであるとともに、該第1カテーテルシャフト内において、前記先端(134)から、前記薬剤搬送用ポート(130)よりも基端側に位置しかつ前記第1カテーテルシャフトからガイドワイヤ(136)を出させるための開口(132)を画成している終点までにわたって延在するガイドワイヤ用管腔(116)を備えた第1カテーテルシャフトと、基端、先端、および、これら基端と先端との間にわたって延在する管腔でありかつ前記第1カテーテルシャフトを受領するための管腔を備えた第2カテーテルシャフト(110)と、を具備してなり、前記第2カテーテルシャフトの前記先端には、ステント配置手段(120)が設けられていることを特徴とするステント配置型薬剤搬送用カテーテル。

【請求項2】 前記第2カテーテルシャフト(110)は、さらに、前記薬剤搬送用ポート(130)よりも先端側に位置する第1閉塞バルーン(122)と、該第1閉塞バルーン(122)に対して流体の流通が可能に連通している膨張用管腔(118)と、を備えることを特徴とする請求項1記載のステント配置型薬剤搬送用カテーテル。

【請求項3】 前記第2カテーテルシャフトは、さらに、前記薬剤搬送用ポート(130)よりも基端側に位置する第2閉塞バルーン(124)を備え、前記ガイドワイヤ用管腔(116)の前記終点は、前記第2閉塞バルーン(124)よりも基端側に位置していることを特徴とする請求項2記載のステント配置型薬剤搬送用カテーテル。

【請求項4】 前記膨張用管腔(118)は、前記第1閉塞バルーン(122)および前記第2閉塞バルーン(124)に対して、流体の流通が可能に連通していることを特徴とする請求項3記載のステント配置型薬剤搬送用カテーテル。

【請求項5】 前記薬剤搬送用管腔(114)に対して流体の流通が可能に連通している複数の薬剤搬送用ポート(130)が設けられていることを特徴とする請求項1記載のステント配置型薬剤搬送用カテーテル。

【請求項6】 前記閉塞バルーン(122、124)は、膨張可能なラバースチックチューブを備えることを特徴とする請求項3記載のステント配置型薬剤搬送用カテーテル。

【請求項7】 前記閉塞バルーン(122、124)は、プローグ成形されていることを特徴とする請求項3記

載のステント配置型薬剤搬送用カテーテル。

【請求項8】 さらに、前記第1カテーテルシャフトの少なくとも一部を通しての血液流通を可能とするための灌流手段を備えることを特徴とする請求項2記載のステント配置型薬剤搬送用カテーテル。

【請求項9】 さらに、灌流のために、前記第1カテーテルシャフト内に、付加的な管腔を備えることを特徴とする請求項3記載のステント配置型薬剤搬送用カテーテル。

【請求項10】 さらに、前記第1カテーテルシャフトの壁において、前記閉塞バルーン(122、124)よりも基端側に、前記付加的な管腔に対して流体の流通が可能に連通している少なくとも1つの開口を備えることを特徴とする請求項9記載のステント配置型薬剤搬送用カテーテル。

【請求項11】 さらに、前記第2カテーテルシャフト上に設けられた膨脹バルーン(120)と、該膨脹バルーン(120)に対して流体の流通が可能に連通しているようにして前記第1カテーテルシャフトに設けられた膨脹用管腔(112)と、を備えることを特徴とする請求項1記載のステント配置型薬剤搬送用カテーテル。

【請求項12】 さらに、前記第2カテーテルシャフト上に設けられた膨脹バルーン(120)と、該膨脹バルーン(120)に対して流体の流通が可能に連通しているようにして前記第1カテーテルシャフトに設けられた膨脹用管腔(112)と、を備え、

前記膨脹バルーン(120)は、前記閉塞バルーン(122、124)どうしの間に配置されていることを特徴とする請求項3記載のステント配置型薬剤搬送用カテーテル。

【請求項13】 前記付加的な管腔は、テーパ状先端を有していることを特徴とする請求項9記載のステント配置型薬剤搬送用カテーテル。

【請求項14】 先端部、先端(134)、および、基端を有するカテーテルシャフト(110)と、該カテーテルシャフト(110)の前記先端部に取り付けられたステント配置手段(120)と；前記カテーテルシャフト(110)に対して前記ステント配置手段(120)よりも先端側位置に取り付けられた第1閉塞バルーン(122)と；前記カテーテルシャフト(110)に対して前記ステント配置手段(120)よりも基端側位置に取り付けられた第2閉塞バルーン(124)と；を具備してなり、

前記カテーテルシャフト(110)は、さらに、前記ステント配置手段(120)と前記閉塞バルーン(122、124)のうちの少なくとも一方との間ににおいて、前記カテーテルシャフト(110)の前記先端部に設けられた少なくとも1つの薬剤搬送用ポート(130)と、

前記閉塞バルーン(122、124)に対して流体の

流通が可能に連通した少なくとも1つの膨らませ用管腔(118)と、前記薬剤搬送用ポート(130)に対して流体の流通が可能に連通した少なくとも1つの薬剤搬送用管腔(114)と、

前記カーテルシャフト(110)の前記先端部内に設けられたガイドワイヤ用管腔(116)と、を備え、前記ガイドワイヤ用管腔(116)は、前記カーテルシャフト(110)の前記先端(134)において前記カーテルシャフト(110)の外部へと開口する第1開口、および、前記カーテルシャフト(110)のうちの前記第2閉塞バルーン(124)よりも基端側であってかつ前記カーテルシャフト(110)の前記基端部よりも実質的に先端側に位置する前記先端部において前記カーテルシャフト(110)の外部へと開口する第2開口(132)を有し、

これにより、ガイドワイヤ(136)は、前記第1開口を通して前記カーテルシャフト(110)内に入ることができ、また、前記第2開口(132)を通して前記カーテルシャフトから出ることができることを特徴とするステント配置型薬剤搬送用カーテル。

【請求項15】 前記カーテルシャフト(110)は、一体物であることを特徴とする請求項14記載のステント配置型薬剤搬送用カーテル。

【請求項16】 先端部、先端、および基端を備えるカーテルシャフト(401)と；該カーテルシャフトの前記先端部に取り付けられた膨張バルーン(412)と；を具備してなり、前記膨張バルーンは、外層(430)および内層(420)を有し、

前記内層(420)は、前記カーテルシャフト(401)近傍に内部領域を形成し、

前記外層(430)および内層(420)は、外部領域を形成し、

前記外層(430)は、複数の開口(428)を有し、前記カーテルシャフト(401)は、さらに、前記外側領域に対して流体の流通が可能に連通した第1管腔と、前記内側領域に対して流体の流通が可能に連通した第2管腔と、ガイドワイヤ(418)を収容するために前記カーテルシャフトの前記先端部内に設けられた第3管腔と、を備え、

前記第3管腔は、前記カーテルシャフト(401)の前記先端(419)において前記カーテルシャフト(401)の外部へと開口する第1開口、および、前記カーテルシャフト(401)のうちの前記膨張バルーン(412)よりも基端側であってかつ前記カーテルシャフト(401)の前記基端部よりも実質的に先端側に位置する前記先端部において前記カーテルシャフト(401)の外部へと開口する第2開口(417)を有し、

これにより、前記ガイドワイヤ(418)は、前記第1開口を通して前記カーテルシャフト内に入ることができ、また、前記第2開口(417)を通して前記カーテルシャフトから出ることができ、

前記カーテルシャフト(401)の前記先端部には、ステント配置手段(412)が設けられていることを特徴とするステント配置型薬剤搬送用カーテル。

【請求項17】 前記第1管腔は、薬剤を搬送し得るよう構成されており、前記第2管腔は、膨張用流体を搬送し得るよう構成されていることを特徴とする請求項16記載のステント配置型薬剤搬送用カーテル。

【請求項18】 先端部、先端、および基端を備えるカーテルシャフト(401)と；該カーテルシャフト(401)の前記先端部に取り付けられた薬剤搬送用バルーン(412)と；を具備してなり、

前記薬剤搬送用バルーン(412)は、該バルーンを貫通して延在する複数のポート(428)を有し、前記カーテルシャフト(401)は、さらに、前記薬剤搬送用バルーン(412)に対して流体の流通が可能に連通した少なくとも1つの搬送用管腔、および、ガイドワイヤ(418)を収容するために前記カーテルシャフトの前記先端部内に設けられた管腔(406)を備え、

該管腔(406)は、前記カーテルシャフト(401)の前記先端(419)において前記カーテルシャフトの外部へと開口する第1開口、および、前記カーテルシャフト(401)のうちの前記薬剤搬送用バルーン(412)よりも基端側であってかつ前記カーテルシャフト(401)の前記基端よりも実質的に先端側に位置する前記先端部において前記カーテルシャフト(401)の外部へと開口する第2開口(417)を有し、

これにより、前記ガイドワイヤ(418)は、前記第1開口を通して前記カーテルシャフト(401)内に入ることができ、また、前記第2開口を通して前記カーテルシャフト(401)から出ることができ、

前記カーテルシャフト(401)の前記先端部には、ステント配置手段(412)が設けられていることを特徴とするステント配置型薬剤搬送用カーテル。

【請求項19】 サラに、灌流用管腔を具備することを特徴とする請求項18記載のステント配置型薬剤搬送用カーテル。

【請求項20】 前記灌流用管腔は、前記カーテルシャフト(401)の前記先端から、前記カーテルシャフト(401)の前記基端までにわたって、延在していることを特徴とする請求項19記載のステント配置型薬剤搬送用カーテル。

【請求項21】 前記灌流用管腔は、前記カーテルシャフト(401)の前記先端(419)から、前記薬剤搬送用バルーン(412)よりも基端側の終点までにわ

たって延在しており。

前記カーテルシャフト(401)は、さらに、前記灌流用管腔の前記終点近傍に位置するとともに、前記灌流用管腔内に血液が入り得るよう、前記灌流用管腔に連通するように前記カーテルシャフト(401)を貫通して延在する少なくとも1つのポートを備えていることを特徴とする請求項1・9記載のステント配置型薬剤搬送用カーテル。

【請求項22】 前記灌流用管腔は、テーパ状先端を有していることを特徴とする請求項21記載のステント配置型薬剤搬送用カーテル。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、バルーン膨張型薬剤搬送用カーテルおよびステント配置型薬剤搬送用カーテルに関するものであって、カーテルシャフト内において終端するガイドワイヤ用管腔と、ガイドワイヤをカーテルシャフトから出すための開口と、を備えている。

【0002】

【従来の技術】経皮管動脈形成術(「PTA」)および経皮管冠状動脈形成術(「PTCA」)は、膨張バルーンが血管系を通して狭窄部位へと進められ障壁を開放するために膨張バルーンを膨張させるものであって、今日では、通常的な手術法である。しかしながら、このような手術の約3分の1においては、再狭窄が発生してしまい、さらなる拡張手術が必要とされている。

【0003】再狭窄を低減させ得る様々な薬剤を、狭窄部位に適用することができる。例えば、ヘパリンのような抗血栓崩壊剤は、閉塞を防止することができる。トロンボゲン形成は、再狭窄をもたらし得るような様々な事象を引き起こすことができる。デキサメタゾンのような抗増殖剤は、円滑な筋肉細胞の移動や増殖を防止することができる。

【0004】そのような薬剤を拡張部位へと有効に搬送するために、様々な方法が提案されている。例えば、Wolinsky氏の米国特許第5,087,244号には、複数の小孔が形成された薄肉フレキシブルバルーンを備えたカーテルが、開示されている。血管形成術の完了後に、そのようなバルーンは、拡張部位へと進められ、そして、ヘパリンや他の薬剤によって膨張される。薬剤は、小孔を通して、動脈壁と接触している膨張バルーンから放出される。

【0005】また、Wolinsky氏の米国特許第4,824,436号および米国特許第4,636,195号には、薬剤搬送用コンジットを備えたカーテルが、開示されている。薬剤搬送用コンジットは、一対の閉塞バルーンどうしの間に設けられている。一対の閉塞バルーンどうしの間に、同一のカーテルを使用しての膨張と薬剤搬送との双方を可能とする膨張バルーンが設

けられた実施形態が開示されている。

【0006】Shockley氏他の米国特許第4,994,033号には、他の膨張用かつ薬剤搬送用のカーテルが開示されている。この場合には、外側層内に複数の小孔が形成された二重層バルーンが設けられている。薬剤は、2つの層どうしの間に導入され、バルーンの内部には、膨張用液体が導入される。膨張用液体の圧力によって、狭窄が膨張されるとともに、薬剤が、拡張された組織に対して直接的に適用される。

【0007】

【発明が解決しようとする課題】薬剤搬送用かつ膨張用のカーテルは、典型的には、カーテルのシャフト全体を貫通して延在しているガイドワイヤ用管腔内に収容されたガイドワイヤに沿って、拡張部位にまで進められる。ガイドワイヤとカーテルとの間の摩擦力のために、カーテルの前進および取外しが、困難なものとなり、時間のかかるものとなっている。

【0008】加えて、カーテル全体がガイドワイヤを覆っていることにより、ワイヤを覆うカーテルを挿入または交換する場合には、ガイドワイヤが、カーテルの長さよりも長い長さだけ患者の身体から突出している必要がある。このようなガイドワイヤは、長さが約300cmであり、体外にある部分は、約230cmである。そうでなければ、ガイドワイヤを固定することができず、狭窄近傍における配置を維持することができない。このような長いガイドワイヤに代えて、カーテルの交換時に、交換ワイヤを、ガイドワイヤのうちの体外にある部分に対して連結することができる。交換ワイヤは、長さが少なくとも180cmであることが必要である。いずれの場合においても、長いワイヤを取り扱うために、操作時には、付加的な操作者が必要である。付加的な操作者がいるにしても、交換時のカーテルの操作は、不便なものである。したがって、手術の長さおよび費用が、無用に増大してしまう。

【0009】

【課題を解決するための手段】本発明のある実施形態においては、先端、この先端の近傍に位置する少なくとも1つの薬剤搬送用ポート、および、この薬剤搬送用ポートに対して薬剤を供給するための少なくとも1つの薬剤搬送用管腔を備えるカーテルシャフトを具備してなる薬剤搬送用カーテルを提案している。カーテルシャフトは、さらに、カーテルシャフト内において、カーテルシャフトの先端から終点までにわたって延在するガイドワイヤ用管腔を備えている。終点は、薬剤搬送用ポートよりも基端側に配置されており、終点の近傍には、ガイドワイヤをカーテルシャフトから出すための開口が形成されている。したがって、カーテルシャフトは、体外にわたって延在するガイドワイヤのほんの一部を覆うだけあり、長いガイドワイヤや、交換ワイヤを必要としない。好ましくは、薬剤搬送領域を隔離する

ために、閉塞バルーンが設けられる。また、灌流のための付加的な管腔が設けられることが好ましい。灌流用管腔の先端は、テーパ状とされていることが好ましい。

【0010】本発明の他の実施形態においては、先端部、先端、および基端を備えるカーテルシャフトを具備する膨張型薬剤搬送用カーテルを提案している。カーテルシャフトの先端部には、膨張バルーンが取り付けられる。カーテルシャフトに対して膨張バルーンよりも先端側位置には、第1閉塞バルーンが取り付けられ、カーテルシャフトに対して膨張バルーンよりも基端側位置には、第2閉塞バルーンが取り付けられる。カーテルシャフトは、さらに、膨張バルーンと閉塞バルーンのうちの少なくとも一方との間ににおいて、カーテルシャフトの先端部に、少なくとも1つの薬剤搬送用ポートを備えている。膨張用バルーンに対して流体の流通が可能に連通した少なくとも1つの膨張用管腔が設けられる。閉塞用バルーンに対して流体の流通が可能に連通した少なくとも1つの膨らませ用管腔が設けられる。薬剤搬送用ポートに対して流体の流通が可能に連通した少なくとも1つの薬剤搬送用管腔が、同様に設けられる。【0011】カーテルシャフトの先端部には、ガイドワイヤ用管腔が設けられる。ガイドワイヤ用管腔は、カーテルシャフトの先端においてカーテルシャフトの外部へと開口する第1開口、および、カーテルシャフトのうちの第2閉塞バルーンよりも基端側であってかつカーテルシャフトの基端部よりも実質的に先端側に位置する先端部においてカーテルシャフトの外部へと開口する第2開口を有している。ガイドワイヤは、第1開口を通してカーテルシャフトに入ることができ、また、第2開口を通してカーテルシャフトから出ることができる。上述のように、カーテルシャフト全体がガイドワイヤを覆っていないことにより、長いガイドワイヤも、交換ワイヤも、必要ではない。さらに、狭窄部位の拡張と薬剤搬送との両方を同一のカーテルでもって行い得ることにより、拡張後の狭窄部位への再配置およびカーテル置換のための時間遅れといった問題が、回避される。

【0012】本発明による膨張型薬剤搬送用カーテルのまた別の実施形態においては、カーテルシャフトの先端部に取り付けられた膨張バルーンは、外層および内層を有している。内層は、カーテルシャフト近傍に内部領域を形成し、外層および内層は、外部領域を形成する。外層は、複数の開口を有している。第1管腔は、外側領域に対して流体の流通が可能に連通しており、第2管腔は、内側領域に対して流体の流通が可能に連通している。カーテルシャフトの先端部には、ガイドワイヤを収容するための、第3管腔が設けられている。第3管腔は、カーテルシャフトの先端においてカーテルシャフトの外部へと開口する第1開口、および、カーテルシャフトのうちの膨張バルーンよりも基端側であつ

てかつカーテルシャフトの基端部よりも実質的に先端側に位置する先端部においてカーテルシャフトの外部へと開口する第2開口を有している。ガイドワイヤは、第1開口を通してカーテルシャフトに入ることができ、また、第2開口を通してカーテルシャフトから出ることができる。

【0013】本発明のさらなる実施形態においては、複数のポート付きの薬剤搬送用バルーンが、カーテルシャフトの先端部に取り付けられている。カーテルシャフトは、さらに、薬剤搬送用バルーンに対して流体の流通が可能に連通した少なくとも1つの搬送用管腔、および、ガイドワイヤを収容するためにカーテルシャフトの先端部内に設けられた管腔と、を備えている。ガイドワイヤ用管腔は、カーテルシャフトの先端においてカーテルシャフトの外部へと開口する第1開口、および、カーテルシャフトのうちの薬剤搬送用バルーンよりも基端側であってかつカーテルシャフトの基端部よりも実質的に先端側に位置する先端部においてカーテルシャフトの外部へと開口する第2開口を有している。この場合においても、ガイドワイヤは、第1開口を通してカーテルシャフトに入ることができ、また、第2開口を通してカーテルシャフトから出ることができます。また、灌流のための管腔が設けられることが好ましい。灌流用管腔は、テーパ状先端を有していることが好ましい。

【0014】本発明のさらなる実施形態においては、薬剤搬送手段は、同一カーテルシャフト内において、空間膨張とバルーン膨張可能ステントの配置との双方と組み合わされている。

【0015】

【発明の実施の形態】図1は、本発明の一実施形態による薬剤搬送用カーテルを示す図であって、カーテルの先端部については、拡大して断面で図示されている。図2は、図1に示すカーテルの先端部を、図1の2-2線に沿って示す断面図である。図3は、図1に示すカーテルの先端部を、90°回転して示す断面図である。図4は、図3に示すカーテルの先端部を、図3の4-4線に沿って示す断面図である。図5は、図1に示すカーテルの基端部を、図1の5-5線に沿って示す断面図である。図6は、図3に示すカーテルを、膨張した閉塞バルーンとともに示す平面図である。図7は、本発明の第2実施形態の先端部を、平面と断面とで示す図である。図8は、本発明の第3実施形態の先端部を、平面と断面とで示す図である。図9は、本発明の第4実施形態を、平面と断面とで示す図である。図10～図13は、本発明の第5実施形態を示す図である。

【0016】図1～図6は、本発明による薬剤搬送用カーテル10の一実施形態を示している。図1においては、カーテル10の先端部が、拡大して断面で示されている。カーテル10は、カーテルシャフト12を

備えている。好ましくは、2つの閉塞バルーン22、24が、カーテルシャフト12の先端部に取り付けられている。カーテルシャフト12の先端26から閉塞バルーン24近傍の終点14aまでにわたって延在する第1管腔14が、ガイドワイヤ28を容し得るよう設けられている。開口30が、終点14a近傍において、カーテルシャフト12の壁に形成されている。好ましくは、第1管腔14は、カーテルシャフト12の周縁部近傍に配置されている。ガイドワイヤ28は、カーテルシャフト12の先端部26における開口31を通って、カーテルシャフト12の第1管腔14内へと入ることができ、そして、開口30から出ることができる。開口30は、実質的には、カーテル10の基端部の先端側に位置している。第1管腔の直径は、約0.022インチ(0.56mm)とすることができる。ガイドワイヤ28の先端部は、図1に示すように、使用時において、管腔14の先端から突出している。カーテルの先端と開口30との間の距離は、約5~25cmであることが好ましい。薬剤搬送用カーテル10の総長さは、より長いあるいはより短い長さが可能であるけれども、120~160cmから始めることができる。ガイドワイヤ28が開口30を通ってカーテルシャフト12から出ることが可能であることにより、過度に長いワイヤを使用する必要がない。また、交換ワイヤを使用する必要がない。というのは、身体から取り外すときに、は、体外にわたって延在するガイドワイヤのはんの一部だけが、カーテル10によって覆われるからである。したがって、本発明のカーテル10が身体内に挿入されるあるいは取り外されるときには、ガイドワイヤには、所定位置に保持されるための十分な余裕空間が存在する。本発明によるカーテル10においては、ガイドワイヤ28は、身体から約7.5cm突出するだけである。

【0017】好ましくは、第2管腔16が、また、カーテルシャフト12の先端26から、閉塞バルーン24近傍の終点14aまでにわたって、延在している。第2管腔の直径は、約0.013インチ(0.33mm)とすることができる。好ましくは、複数のポート32が、第2管腔16に連通するよう、カーテルシャフト12の壁を通して形成されている。複数のポート32は、以下においてさらに説明するように、管腔を通しての血液の能動灌流を可能とすることができます。直径または長さがそれぞれ約0.003~0.020インチ(0.076~0.51mm)の、2~20個の円形または梢円形のポート32が、設けられていることが好ましい。本実施形態においては、3個の灌流用開口32が設けられている。また、基端閉塞バルーン24と開口30との間に、同様に、第1管腔14を通しての血液の灌流を可能とするための、第1管腔14に連通するポート30aを設けることができる。第2管腔16の先端16bは、図

1に示すように、テーパ状であることが好ましい。これにより、先端16bにおける開口が見えにくくなり、使用時に、第1管腔14に間違えて、第2管腔16内にガイドワイヤ28を挿入してしまうことが防止される。このような構成に代えて、管腔16を、カーテルシャフト12の長さ全体にわたって延在させても良く、これにより、以下説明するように、血液や從来から知られている過フルオロ化合物または再結合性ヘモグロビンの能動灌流が可能となる。

【0018】図2は、図1の2~2線に沿う断面図であって、第1管腔14および第2管腔16、ポート32、さらに、第3管腔18および第4管腔20を示している。第3管腔18および第4管腔20について、図3を参照して説明する。

【0019】図3は、カーテル10の先端部を、90°回転して示す断面図である。ガイドワイヤ28は、図示省略されている。図においては、第3管腔18が示されている。この第3管腔18は、閉塞バルーン22、24に対して、カーテルシャフト12を貫通するポート34を通して、膨張用液体を供給するためのものである。好ましくは、バルーン22、24の双方を膨らますために、単一の管腔18が使用される。第3管腔18の直径は、約0.010(0.25mm)とすることができる。同様に、各バルーン22、24に対して隔離された複数の管腔を設けることもできる。

【0020】薬剤を搬送するための第4管腔20が、また、図示されている。閉塞バルーンどうしの間には、少なくとも1つの薬剤搬送用ポート36が、カーテルシャフト12を貫通して、第4管腔20に連通するよう設けられている。第4管腔20の直径は、約0.010(0.25mm)とすることができる。膨張部位に対する適切な薬剤の搬送を確実なものとするために、直径または長さがそれぞれ約0.003~0.020インチ(0.076~0.51mm)の、2~20個の円形または梢円形のポート36が、設けられていることが好ましい。図3においては、このようなポートは3個である。任意の所望の薬剤は、膨張部位に対して、第4管腔20により搬送することができる。図4は、カーテルシャフト12の図3の4~4線による断面図であって、図3における複数の管腔の配置状況が示されている。また、付加的な薬剤搬送用管腔を、設けることができる。

【0021】閉塞バルーン22、24は、薬剤搬送時には、膨張部位を隔離し得ることが好ましい。閉塞バルーン22、24は、動脈壁のうちの既に膨らませられた部分の近傍に薬剤を維持する。これにより、薬剤の吸収および有効性が向上する。図6は、図3の向きのカーテル10の平面図であって、薬剤搬送の直前および薬剤搬送時に膨らませられた閉塞バルーン22、24が示されている。開口30、および、開口30から出ているガイドワイヤ28、さらに、薬剤搬送用ポート36もまた、図示

されている。この図においては、灌流用開口32は、カテーテルの向こう側に位置している。

【0022】複数の管腔を備えた一体型のカテーテルシャフト12に代えて、カテーテルシャフト12は、互いに適切に接着された複数のチューブを備えることができる。加えて、図6において拡大して示すカテーテルシャフト12の先端部は、シャフトの他の部分よりも、より柔らかい材料から形成形成することができる。先端部が柔らかい材料から形成されていると、血管系を通しての操作性を向上させることができる。一方、シャフトの残りの部分が、より硬い材料から形成されると、押込性を良好とすることができます。これら2つの部分は、従来技術において知られているような熱接着あるいは接着剤により、単に結合させることができます。適切な材料については、後述する。カテーテル10の硬さおよび押込性をさらに向上させるために、ステンレス鋼製のあるいはタンクステン製のワイヤ(図示せず)を、また、カテーテルシャフト12の基端部に設けることができる。

【0023】再度図1を参照すると、カテーテル10の基端部には、カテーテルシャフト12に接続された2つのチューブ72、74が設けられている。一方のチューブは、肺脈用液体の供給のためのものであって、第3管腔18に接続されている。他方のチューブは、薬剤の供給のためのものであって、第4管腔20に接続されている。各チューブには、ハブ78が連結されている。チューブ72、74を通して、閉塞パルーン22、24に対して肺脈用液体を供給するために、また、任意の所望の薬剤を供給するために、シリジンを使用することができます。カテーテル10が能動灌流のために適用されており、かつ、第2管腔16がカテーテルシャフト12の基端部にまで延長している場合には、第3のチューブ(図示せず)を、第2管腔16に対して、取り付けることができる。附加的な管腔が設けられている場合には、カテーテルシャフト12に対して、附加的なチューブを取り付けることができる。あるいは、Yアダプタを取り付けることができる。図5は、カテーテルシャフトを、図1の5-5線に沿って示す断面図であって、第3管腔18および第4管腔20が示されている。

【0024】カテーテル10、および、すばんだ状態での閉塞パルーン22、24の外径は、約0.056インチ(1.42mm)を超えないことが好ましい。これにより、7または8フレンチガイドカテーテル(7 or 8 French guiding catheter)とともに使用することができる。

【0025】チューブ72、74を受容し得るよう、内側カテーテルシャフトの基端部52は、おおよそ場所80において、約0.140インチ(3.56mm)の外径にまで拡張している。チューブ72、74は、熱収縮チューブ82により、互いに保持されている。チューブ72、74は、熱接着または接着剤により、カテーテル

シャフトに対して連結されている。

【0026】第1管腔14の先端26は、好ましくは、カテーテルシャフト12の材料と比較して、より柔らかな材料を有する弹性チップ96を備えている。チップ96は、生体組織に接触したときに、広がる、または、曲がる。これにより、血管系を通してのカテーテルの通過が容易とされ、組織の損傷の防止に役立つ。チップ96は、Dow Chemical Corporationによる超低密度ポリエチレン4603から形成することができる。この材料は、190°Cにおいて0:7~0.9g/10minのメルトフローインデックス(ASTM D-1238)、および、0.9030~0.9070g/ccの密度(ASTM D-792)を有している。チップ96は、また、Elf Atochem Deutschland GmbHによるPEBA 25Dのような、ナイロンあるいはポリアミドコポリマーとすることができる。この材料は、最小4950psiの引張強度(ASTM D-638)、最小640%の伸び(ASTM D-638)、最小21000psiのたわみ率(ASTM D-790)、25D±4Dのデュロメーター(ASTM D-2240)、および、142°C~153°Cの融点(ASTM D-3418)を有している。チップ96は、接着剤または熱接着により、カテーテルシャフト12に対して連結することができます。

【0027】また、例えば金またはタンタル製の放射線に対しても不透明なマーカー98が、従来から知られているように、PTAまたはPTCA手術時におけるX線透視法によるカテーテルの位置観測のために、図1に示すように閉塞パルーン22、24内において、カテーテルシャフト12に、設けられることが好ましい。このようなマーカーは、他の配置、例えば、最後方のポート32の基端に、設けることもできる。

【0028】カテーテルシャフト12、および、閉塞パルーン22、24は、好ましくは、シリコン、アクリルイミド、あるいは親水性ポリウレタンコーティングのようないかだり滑り材料でコーティングされている。これにより、従来から知られているように、ガイドリングカテーテルを通しての、本発明による薬剤搬送用カテーテル10の通過が容易とされる。

【0029】カテーテルシャフトは、カテーテルにとって適切な任意の材料、例えば、線形低密度ポリエチレンまたは高密度ポリエチレン、ナイロン、ポリアミド、ポリアミドコポリマー、ポリウレタン、ポリプロピレン、ポリエチステルコポリマー、シリコーンラバー、あるいは、他の非トルボポゲン形成材料から形成することができる。ステンレス鋼製の、あるいは、ニチノール(Nitinol)製の、同様に、例えばRaychem Corporationから入手可能なニッケルチタン合金製の、金属チューブを使用することもできる。

【0030】適切な線形低密度ポリエチレンは、Dow Chemical CompanyによるDowlex 2038である。この材料は、190°Cにおいて0.85~1.15 g/10 minのメルトフローインデックス(ASTM D-1238)、および、0.933~0.937 g/ccの密度(ASTM D-792)を有している。使用可能な高密度ポリエチレンは、Quantum Chemical CorporationによるLB 8320-00である。この材料は、190°Cにおいて0.20~0.36 g/10 minのメルトフローインデックス(ASTM D-1238)、および、最小0.9566 g/ccの密度(D-1505)を有している。

【0031】使用可能なナイロンは、Huels America Inc. によるL2101F Vestam

引張強度 (ASTM D-638)	e dのようなナイロン12である。この材料は、2.05~2.22の相対粘度(ISO 307)、および、最大0.10の含水率(ASTM D-4109)を有している。使用可能な他のナイロンは、E1f Atoc hemによるPEBA 63Dである。この材料は、最小8300 psiの引張強度(ASTM D-638)、最小400%の伸び(ASTM D-638)、最小67,000 psiのたわみ率(ASTM D-790)、69D±4Dのデュロメーター(ASTM D-2240)、および、160°C~180°Cの融点(ASTM D-3418)を有している。
破裂における伸び、% (ASTM D-638)	【0032】使用可能な高密度ポリエチレンは、Quantum Chemical CorporationによるLM6007である。この材料は、以下の特性を有している。
デュロメーターのD係数 (ASTM D-2240)	最小4400 psi
240°C、2160 gにおける メルトフローインデックス (ASTM D-1238)	最小600%
室温におけるたわみ率 (ASTM D-790、手法B)	68±4.5
Vicat軟化点、°C (ASTM D-1525)	0.070 (REF)

【0033】カーテールシャフト12の先端部がシャフトの他の部分よりも柔らかいことが要望されている場合には、使用可能な適切なナイロンは、E1f Atoc hemによるPEBA 63Dである。この材料は、最小8100 psiの引張強度(ASTM D-638)、最小300%の伸び(ASTM D-638)、最小49,000 psiのたわみ率(ASTM D-790)、63D±4Dのデュロメーター(ASTM D-2240)、および、160°C~180°Cの融点(ASTM D-3418)を有している。

【0034】所望数の管壁を備えたカーテールシャフト12は、従来の押出工程により製作することができる。カーテールシャフト12の拡径部を形成するために、従来技術において知られているように、バンプ押出工程を使用することができる。管壁付きの一体型カーテールシャフト12に代えて、互いに接続された個別の複数のチューブを使用することができる。

【0035】弹性チュップ96は、カーテールシャフト12の先端にチップ材料の小チューブを配置し、そして、所定位置に熱接着することにより、カーテールシャフトに対して取り付けることができる。同様に、接着剤を使用することができる。チューブ材料は、カーテール

シャフト12の増大させてしまう。チップ材料のチューブの配置後に、カーテールシャフト12の外径を約0.056インチ(1.42 mm)よりも小さく維持するために、カーテールシャフトの先端部を、チップ材料の取付に先立って、適切な量だけ、減少させるあるいは“すぼめる(necked-down)”ことができる。管壁14、16を開口状態に維持したまま、弹性チップを熱接着により取り付けるために、各管腔内には、心棒が挿入される。チップ材料のチューブは、カーテールシャフト12のうちの先端閉塞バルーン22が取り付けられている領域にまで、延出することができる。この場合には、バルーン22の全部または一部が、チップ材料に対して取り付けることができる。

【0036】チップ材料の熱接着時には、第3管壁18および第4管壁20の先端部は、閉塞している。どちらかの管腔のより多くの部分を閉塞することが必要な場合には、カーテールシャフト12と同じ材料製の小さな固体チューブが、その管腔の基端内に挿入され、その後、所定位置に熱接着される。接着剤を、同様に、使用することができる。チューブの外径は、前記管腔の直径よりもわずかに大きいことが好ましい。心棒は、他の管腔を開放状態に維持する。弹性チュップ96の取付時に第3管

腔18が閉塞されない場合には、第4管腔と同様にして閉塞することができる。

【0037】第1管腔14および第2管腔16の基端部は、同様にしてシールすることができる。

【0038】閉塞バルーン22、24は、ナイロン、ポリアミド、ポリアミドポリマー、ポリエチレン、ポリエチレンテフロラート、ポリエステルエラストマー、ポリウレタン、カブトン(Kraton)、シリコーン、ラテックス、あるいは、任意の他の柔軟な非トロンボゲン形成材料から形成することができる。閉塞バルーン22、24は、膨らまされたときに、血管壁を膨らまさないものの、血管壁をシールする。バルーンは、膨張によって膨らむチューブとすことができる。あるいは、プロア成形されたバルーンとすることができる。バルーン材料がカテーテルシャフト12に対して適合性を有している場合には、閉塞バルーン22、24は、レーザー接着を含む熱接着技術により、取り付けることができる。カテーテル上にバルーンをレーザー接着するための装置および方法は、米国特許第5,267,959号に開示されている。この文献は、販売のためここに組み込まれる。接着剤を、同様に使用することができる。閉塞バルーン22、24として使用可能なナイロンは、EM S-Chemie AGによるL25G Grillam idである。この材料は、178°Cの融点、1.01kg/dm³の密度(DIN 53479)、40N/m²の引張強度(DIN 53455)、10%の破裂における伸び(DIN 53455)、および、7.2のショア(Shore)D硬度(DIN 53505)を有している。

【0039】本発明の第1実施形態による薬剤搬送用カテーテルは、通常の方法により膨張が達成された後に、PTCA法またはPTCA法による処置部位にまで、薬剤を搬送するために使用することができる。膨張カテーテルは、好ましくは、例えば、Bonne 1氏の米国特許第4,762,129号に開示されているような迅速交換フォーマットからなるものである。この文献は、参考のためここに組み込まれる。このようなカテーテルが、まず最初に、取り外される。本発明の薬剤搬送用カテーテル10が、その後、血管系に導入され、前記膨張カテーテルを狭窄部位にまで案内した同一のガイドワイヤに沿って、ガイドティングカテーテルを介して、膨張部位にまで進められる。交換ワイヤは、一切必要ではなく、ガイドワイヤは、身体から約75cmだけ突出するだけで済む。カテーテル10の第1管腔14の先端が、図1に示すガイドワイヤ28のようなガイドワイヤ内に挿入される。カテーテルがガイドワイヤに沿って進むときには、ガイドワイヤは、カテーテル10の開口30から出ている。カテーテル10は、膨張部位にまで前進される時には、ガイドワイヤのうちの第1管腔14内に位置する部分に沿って搬送され続ける。

【0040】カテーテル10の進み具合は、X線透視法により追跡される。膨張部位に到達したときには、閉塞バルーン22、24が動脈壁に当接して動脈壁をシールするまで、第3管腔18を通して膨らませる。灌流用開口32および30aが存在する場合には、それぞれ、第2管腔16および第1管腔14を通して流れ、カテーテル10の先端部から流出する。カテーテル10が能動灌流を行ひ得るよう構成されている場合には(すなわち、第2管腔16がカテーテルシャフト12の長さ全体にわたって延在している場合には)、血液またはFluosoil(登録商標)のような過フッ素化合物および再結合性ヘモグロビンを、従来技術において知られているように、チューブ76を介してシリジンにより注入することができる。

【0041】抗血栓崩壊剤、抗増殖剤、あるいは任意の他のタイプの薬剤は、ここで、シリジンにより、チューブ72、第4管腔20、さらには薬剤搬送用ポート36を通して注入することができる。有効な薬剤の1つの形態は、実質的に100ミクロンよりも小さな直径のポリ乳酸/ポリグリコール酸粒子に吸着させたディキサタゾンである。このような粒子は、動脈壁に吸着する、あるいは、動脈壁を貫通することができる。粒子表面は、動脈壁に対する粒子の吸着力を高めるために、セル吸着性タンパク質により処理することができる。使用可能なアルギニングリシンアスパラギン酸に基づくペプチドは、Telios Pharmaceuticals, Inc.によるPeptite 2000(登録商標)である。

【0042】所望の圧力で、所望の時間(典型的には、約20秒~3分)にわたって、薬剤が適用された後に、閉塞バルーンは、すばまされ、薬剤搬送用カテーテル10は、血管から迅速にかつ容易に引き抜かれる。

【0043】図7は、本発明の第2実施形態の先端部を平面と断面とで示す図であって、拡張と薬剤搬送との両方を行ひ得るカテーテル100が示されている。カテーテル100は、第1管腔112、第2管腔114、第3管腔116、および第4管腔118を有するカテーテルシャフト110を備えている。カテーテルシャフト110には、膨張バルーン120、および、2つの閉塞バルーン122、124が、取り付けられている。膨張バルーン120は、開口126を通して第1管腔112と流体の連通が可能とされている。両閉塞バルーンは、同様に、開口128を通して第4管腔118と流体の連通が可能とされている。第2管腔114には、カテーテルシャフト110の壁を貫通してポート130が設けられており、このポート130を通して、膨張部位に対する薬剤投与を行なうことができる。上記と同様にして、付加的な薬剤搬送用管腔を設けることができる。付加的な管腔は、膨張バルーン120に対して、あるいは同様に閉塞バルーン122、124に対して、流体を提供すること

ができる。また、第3管腔116には、カーテルシャフト110の壁を貫通して、開口132が設けられている。カーテル100の先端134における開口133を貫通して延在している第3管腔116は、開口132を通してこの管腔116内に存在しているガイドワイヤ136を収容している。付加的な管腔(図示せず)を、また、能動的あるいは受動的な灌流のために設けても良い。そのような灌流用管腔の先端は、上述のように、好ましくはテバ形状とされている。上述のような滑りコーティングが、膨張バルーン120に、および、カーテル100の残りの部分に、適用される。上述のように複数の管腔を有する一体型のカーテルシャフトに代えて、カーテルシャフト110を、互いに適切に結合された複数のチューブから構成することができる。

【0044】膨張バルーン120は、PTA法およびPTCA法にとって適切な任意のタイプおよびサイズのものとすることができます。例えば、バルーン120は、ポリエチレン、ポリエチレンレフレタード、ナイロン、ポリアミド、ポリアミドコポリマー、ポリウレタン、あるいは、膨張バルーンとして適切な他の任意の材料から形成することができる。バルーン120は、柔軟、非柔軟、あるいは、半柔軟とすることができます。膨張バルーン120は、従来技術において知られているように、レーザー接着あるいは超音波接着を含む熱接着により、または接着剤により、カーテルシャフト110に対して取り付けることができる。バルーン120は、熱接着が可能であるように、カーテルシャフト110と同じ材料であるか、または適合性のある材料であることが好ましい。

【0045】膨張バルーン120として使用可能な低密度ポリエチレンは、Rexene CorporationによるP. E. 1031である。この材料は、 $190 \pm 0.2^{\circ}\text{C}$ において $0.4 \sim 1.4 \text{ g}/10\text{ min}$ のメルトフローインデックス(ASTM D-1238)、 $0.93 \pm 0.02 \text{ g}/\text{cc}$ の密度(ASTM D-1505)、および、 $104 \sim 140^{\circ}\text{C}$ の融点(ASTM D-3417、D-3418)を有している。使用可能な線形低密度ポリエチレンは、Dow Chemical CorporationによるDowlex 2247A LL PDEである。この材料は、 $190^{\circ}\text{C} / 2.16 \text{ kg}$ において $2.0 \sim 2.6 \text{ g}/10\text{ min}$ のメルトインデックス(ASTM D-1238)、 $0.9150 \sim 0.9190 \text{ g}/\text{cc}$ の密度(ASTM D-1505)、および、 $122 \sim 125^{\circ}\text{C}$ の融点(D-3417、D-3418 (REF))を有している。

【0046】第1実施形態に関連して上述した材料は、本実施形態における他の対応する部材にとって適切である。第1実施形態と同様に、カーテルシャフト110には、膨張バルーン120の下に、また、閉塞バルーン122、124の下に、放射線不透明マーカー138が

設けられる。カーテル100の基礎の構造は、図1に示すカーテル10の基礎と本質的に同じである。ただし、カーテルシャフト110の基礎には、第1管腔112を通して膨張バルーン120へと膨張用液体を供給するための第3チューブが取り付けられる点だけが相違する。従来技術において知られているように、Yアダプターを、また、使用することができる。

【0047】使用時には、本実施形態のカーテル100は、従来技術において知られているように、ガイドティングカーテルにより狭窄部位にまで既に進められたガイドワイヤ136のようなガイドワイヤに、挿入される。カーテル100内に開口134を通して侵入し、第3管腔116からは開口132を通して出ている。上述のように、カーテル100の一部だけがガイドワイヤと摩擦係合していることにより、カーテルは、狭窄箇所へと容易にかつ迅速に進むことができるとともに、使用するガイドワイヤが短くて済む。適正に配置されたときには、膨張バルーン120は、従来方法により、狭窄部位を開放するために、膨らむことができる。その後、膨張バルーン120をそばまで、上述のように、閉塞バルーン122、124を膨らませることができます。任意の所望の薬剤は、その後に、第2管腔114を通して供給することができます。同一のカーテルでもって拡張と薬剤搬送との両方を行い得ることにより、本実施形態においては、膨張用カーテルを引き抜いてさらに別体の薬剤搬送用カーテルを挿入するのに必要な時間を省くことができ、手術時間を短縮することができます。加えて、本実施形態においては、薬剤搬送用カーテルの適正配置のための、膨張部位への正確な再配置という問題を緩和することができる。

【0048】本発明の第3実施形態においては、カーテル200は、同一の膨張バルーンでもって、狭窄部位の拡張と拡張箇所への薬剤搬送との両方を行うことができる。図8は、このようなカーテル200の先端部を平面と断面とで示す図であって、膨張バルーンが膨張した状態が示されている。カーテル200は、カーテルシャフト210、第1管腔212、第2管腔214、および、第3管腔216を備えている。第2管腔214は、開口219を通してガイドワイヤ218の出口を形成するために、カーテルシャフト210を貫通して、開口217が設けられている。複数の管腔を有する一体型のカーテルシャフトに代えて、カーテルシャフト210は、また、互いに適切に結合された複数のチューブから構成することができる。

【0049】カーテル200のバルーン部は、外バルーン220および内バルーン230を備えている。第2管腔214は、内バルーン230の内部を挿通して延在している。外バルーン220の先端は、内バルーン230の先端に対して、熱または接着剤により接着されてい

る。一方、内バルーン230の先端は、第2管腔214の外表面に対して、場所240において、熱または接着剤により接着されている。外バルーン220および内バルーン230の両基端は、カーテルシャフト210に対して、外バルーンと内バルーンとの中間の領域が第1管腔212と流体連通している状態で、かつ、内バルーン230の内部が第3管腔216と流体連通している状態で、熱または接着剤により接着されている。膨張用流体は、第3管腔216を通して供給され、薬剤は、第1管腔212を通して供給される。複数の微小孔280が、薬剤をバルーンから放出するために、外バルーン220の壁を貫通して形成されている。このような孔は、0.01ミクロン～0.1mmとすることができる。バルーン220の外層が、ポリエチレンテフレタートあるいはナイロンあるいはポリエステルエラストマーのような二輪配向プラスチック材料を備えている場合には、微小孔280は、精度の高いレーザーを使用して形成することができる。

【0050】使用時には、ガイドワイヤ218が、従来方法によりガイドカーテルを介して、処置されるべき障害部位へと進められる。第2管腔214の先端が、ガイドワイヤ218の基端部にわたって取り付けられる。上記両実施形態と同様に、ガイドワイヤは、カーテル200から開口217を通して出ている。カーテル200は、バルーン部が処置されるべき障害部位に到達するまで、ガイドワイヤのうちの第2管腔214内の部分に沿って前進を続ける。図8においては、バルーン部の内層230および外層220が膨張状態で図示されているけれども、これら層は、狭窄部位へと前進する際には、管腔214の外面に対して密着した状態となってい

る。

【0051】放射線不透明マーカーバンド242を利用して、カーテル200の先端部が適切に配置されると、選択された薬剤が、第1管腔212を通して、外バルーン220・内バルーン230の中間領域に、導入される。薬剤の注入は、外バルーン220のいくらかの拡張をもたらすけれども、典型的には、薬剤が注入されるような圧力は、薬剤の量が実質的に微小孔280から放出されてしまうような圧力よりも小さい。薬剤搬送と拡張との両方を同時にうるために、次に、膨張用流体が、第3管腔216を通して、内バルーン230の内部へと、注入される。圧力が増加すると、典型的には7～8気圧に到達すると、バルーンの内層230は、所定最大直径にてまで膨らむ。そして、このように膨らむことにより、特別の薬剤もって処置されている障害部位に対して、ポート280を通して、薬剤を効果的に散布することができる。内バルーン230の膨張により、また、障害部位に対して作用する圧力がもたらされ、薬剤が適用しながら血管壁に対する押し付けを行うことができる。

【0052】本発明の薬剤搬送用カーテルによる膨張

部位に対しての薬剤の搬送のためのバルーンの使用は、図9の第4実施形態に示されている。カーテル300は、上述のように、カーテルシャフト310に対して、熱または接着剤により取り付けられた薬剤搬送用バルーン312を備えている。図9においては、バルーン312は、膨脹状態で示されている。複数の薬剤搬送用ポート314が、バルーン312にわなって設けられている。バルーン312は、カーテルシャフト310の壁を貫通するポート318を通して、薬剤搬送用管腔316と流体連通している。付加的な薬剤搬送用管腔を、また、設けることができる。ガイドワイヤ用管腔320は、先端322を貫通して、カーテルシャフト310の先端部に設けられている。ガイドワイヤ用管腔320は、カーテルシャフト310の先端部のうちの、薬剤搬送用バルーン312の基端側において、終端している。カーテルシャフト310の壁には、ガイドワイヤ用管腔320に連通する開口324が設けられている。ガイドワイヤ326は、カーテルシャフト310の先端322において開口328を通して挿入することができ、また、開口324を通して出すことができる。

【0053】テバ状端部330aが形成された灌流用管腔330を、設けることが好ましい。この管腔は、上述のように、能動灌流を可能とするように、カーテルシャフト310の長さ全体にわたって延在することができる。これに代えて、この管腔は、薬剤搬送用バルーン312の基端側において終端することができる。その場合、能動灌流を可能とするために、第1実施形態と同様にして、複数の開口(図示せず)を、カーテルシャフト310の壁を貫通して設けることができる。複数の管腔を備えた一体型のカーテルシャフトに代えて、カーテルシャフト310を、互いに適切に接着された複数のチューブから構成することができる。

【0054】本願発明の第5実施形態は、バルーン拡張型ステントに、空間膨張機能と局所の薬剤搬送機能とを組み合わせたものである。図10、11、および、図12、13には、それぞれ、非膨張状態および膨張状態を示している。カーテル400は、上述と同様にしてカーテルシャフト401に融着されたまたは接着された二重壁型の膨張用かつ薬剤搬送用のバルーン412と、第1管腔405と、第2管腔406と、第3管腔407と、を備えている。第2管腔406は、開口419を通してガイドワイヤ418を受領している。第2管腔406に対して、カーテルシャフト401を貫通して、開口417が設けられている。この開口417は、ガイドワイヤ418のための出口をなすことができる。複数の管腔が設けられている一体型のカーテルシャフトに代えて、カーテルシャフト401は、また、互いに接着された複数のチューブから構成することもできる。

【0055】二重壁バルーン412は、本発明の第3実施形態における二重壁バルーンと同様のものである。バ

ルーン膨張可能ステント440が、二重壁バルーンに取り付けられている。取付方法は、係合や、バルーン脚張かつステント配置時に二重壁バルーンからステントを取り外し得るような他の任意の方法によって行うことができる。

【0056】使用時には、ガイドワイヤ418が、従来方法によりガイドカテーテルを介して、処置されるべき障害部位へと進められる。第2管腔406の先端419が、ガイドワイヤ418の基礎部にわたって取り付けられる。上記両実施形態と同様に、ガイドワイヤは、カテーテル400から開口417を通してしている。カテーテル400は、バルーン部が処置されるべき障害部位に到達するまで、ガイドワイヤのうちの第2管腔406内の部分に沿って前進を続ける。図10～図13においては、バルーン部の内層430および外層420が膨張状態で図示されているけれども、これら層は、狭窄部位へと前進する際には、管腔419の外面に対して密着した状態となっている。

【0057】放射線不透明マーカーバンド442を利用して、カテーテル400の先端部が適切に配置されると、選択された薬剤が、第3管腔407を通して、外バルーン430・内バルーン420の中間領域に、導入される。薬剤の注入は、外バルーン430のいくらかの拡張をもたらすけれども、典型的には、薬剤が注入されるような圧力は、薬剤の量が實質的に微小孔428から放出されてしまうような圧力よりも小さい。薬剤搬送と狭窄の拡張とステントの配置とを同時に行うために、次に、膨張用流体が、第1管腔405を通して、内バルーンの内部421へと、注入される。圧力が増加すると、典型的には7～8気圧に到達すると、バルーンの内層420は、所定最大直径にまで膨らむ。そして、このように膨らむことにより、特別の薬剤もって処置されている障害部位に対して、薬剤を効果的に散布することができるとともに、ステントを膨張させて血管壁に対してステントを押しつけることができる。薬剤は、外バルーンの孔から放出されて、ステントの格子を通して浸透していく。

【0058】本発明による薬剤搬送用カテーテルおよび膨張型薬剤搬送用カテーテルにおいては、迅速かつ容易なカテーテルの前進および引抜きが可能であり、よって、手術に要する時間を短縮することができる。また、必要な人員および装置を省略することができ、手術コストを低減することができる。

【0059】上記においては、本発明の好ましい実施形態について説明してきたけれども、上記実施形態は、本発明の範囲を制限するものではなく、本発明の範囲は、諸説の範囲によって定義されている。

【図面の簡単な説明】

【図1】 本発明の一実施形態による薬剤搬送用カテーテルを示す図であって、カテーテルの先端部については、拡大して断面で図示されている。

【図2】 図1に示すカテーテルの先端部を、図1の2～2線に沿って示す断面図である。

【図3】 図1に示すカテーテルの先端部を、90°回転して示す断面図である。

【図4】 図3に示すカテーテルの先端部を、図3の4～4線に沿って示す断面図である。

【図5】 図1に示すカテーテルの基礎部を、図1の5～5線に沿って示す断面図である。

【図6】 図3に示すカテーテルを、膨張した閉塞バルーンとともに示す平面図である。

【図7】 本発明の第2実施形態の先端部を、平面と断面とで示す図である。

【図8】 本発明の第3実施形態の先端部を、平面と断面とで示す図である。

【図9】 本発明の第4実施形態を、平面と断面とで示す図である。

【図10】 本発明の第5実施形態を示す図である。

【図11】 本発明の第5実施形態を示す図である。

【図12】 本発明の第5実施形態を示す図である。

【図13】 本発明の第5実施形態を示す図である。

【符号の説明】

400 カテーテル

401 カテーテルシャフト

405 管腔

406 管腔

407 管腔

412 バルーン

417 第2開口

418 ガイドワイヤ

419 先端

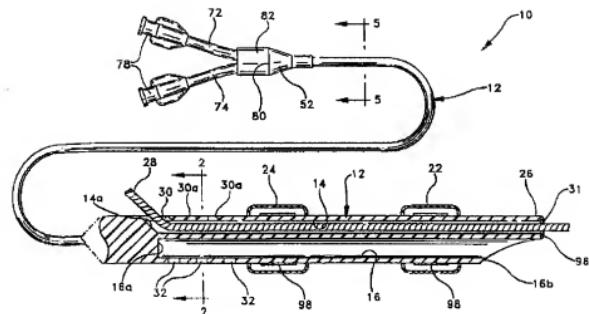
420 内層

428 (薬剤放出のための) 開口

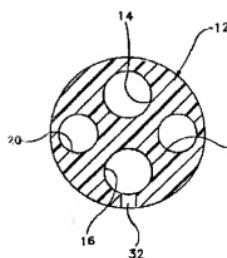
430 外層

440 ステント

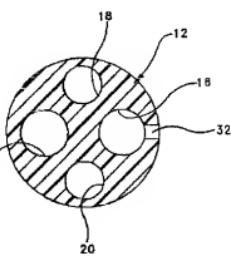
【図1】



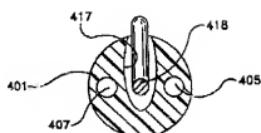
【図2】



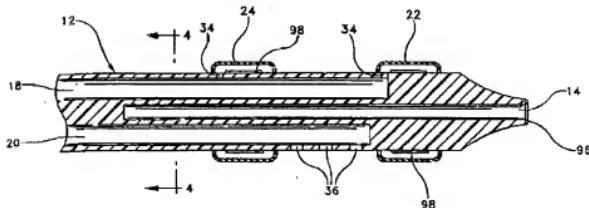
【団4】



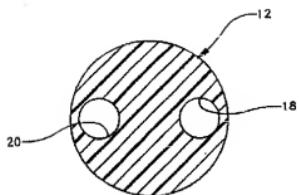
【団11】



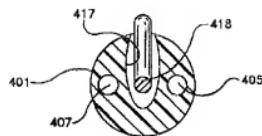
【団3】



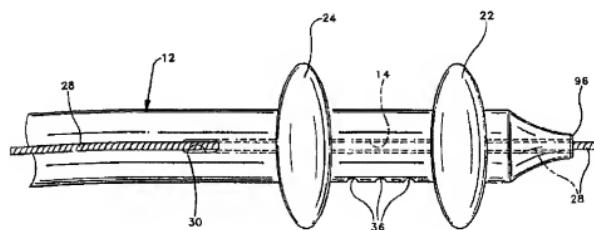
【図5】



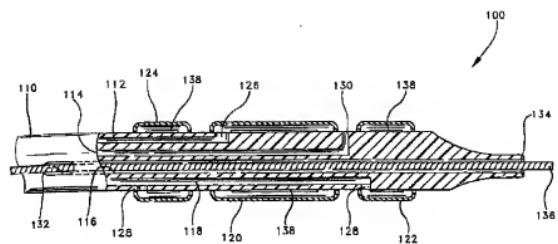
【図13】



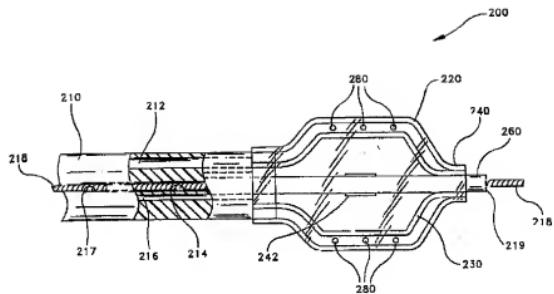
【図6】



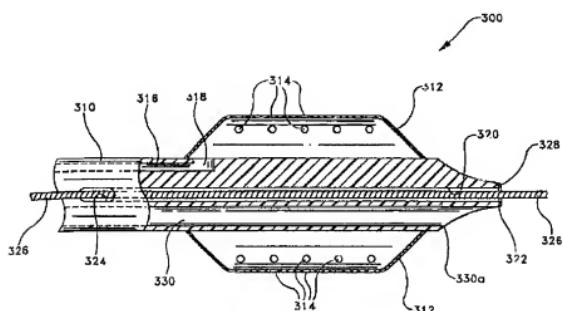
【図7】



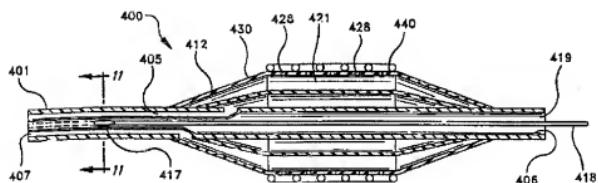
【図8】



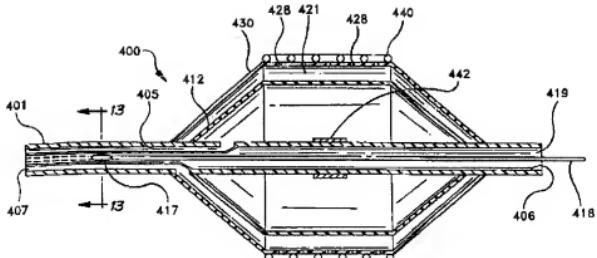
【図9】



【図10】



【図12】



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CLAIMS**[Claim(s)]**

[Claim 1]It is a catheter for stent deployment type drugs conveyance characterized by comprising the following, While being the 1st catheter shaft provided with at least one lumen (114) for drugs conveyance for supplying drugs to at least one port (130) for drugs conveyance in which it is located near a tip and this tip, and this port (130) for drugs conveyance, it is inside of this 1st catheter shaft.

From said tip (134), The 1st catheter shaft provided with a lumen (116) for guidewires which migrates even to a terminal point which is forming an opening (132) for being located in the end face side rather than said port (130) for drugs conveyance, and making a guidewire (136) take out from said 1st catheter shaft, and extends.

The 2nd catheter shaft (110) that is a lumen which extends over a end face, a tip, and these end faces and a tip, and was provided with a lumen for receiving said 1st catheter shaft. It provides and is a stent deployment means (120) at said tip of said 2nd catheter shaft.

[Claim 2]The catheter for stent deployment type drugs conveyance according to claim 1 characterized by comprising the following.

The 1st blockade balloon (122) in which said 2nd catheter shaft (110) is further located in the tip side rather than said port (130) for drugs conveyance.

A lumen (118) for expansion which circulation of a fluid is opening for free passage possible to this 1st blockade balloon (122).

[Claim 3]Said 2nd catheter shaft is further provided with the 2nd blockade balloon (124) located in the end face side rather than said port (130) for drugs conveyance, The catheter for stent deployment type drugs conveyance according to claim 2, wherein said terminal point of said lumen (116) for guidewires is located in the end face side rather than said 2nd blockade

balloon (124).

[Claim 4]The catheter for stent deployment type drugs conveyance according to claim 3, wherein circulation of a fluid is opening said lumen (118) for expansion for free passage possible to said 1st blockade balloon (122) and said 2nd blockade balloon (124).

[Claim 5]The catheter for stent deployment type drugs conveyance according to claim 1, wherein two or more ports (130) for drugs conveyance which circulation of a fluid is opening for free passage possible to said lumen (114) for drugs conveyance are provided.

[Claim 6]The catheter for stent deployment type drugs conveyance according to claim 3, wherein said blockade balloon (122, 124) is provided with a plastic tube which can expand.

[Claim 7]The catheter for stent deployment type drugs conveyance according to claim 3, wherein blow molding of said blockade balloon (122, 124) is carried out.

[Claim 8]The catheter for stent deployment type drugs conveyance according to claim 2 provided with an inflow means for enabling blood circulation which lets said at least a part of 1st catheter shaft pass.

[Claim 9]The catheter for stent deployment type drugs conveyance according to claim 3 having an additional lumen in said 1st catheter shaft for inflow.

[Claim 10]The catheter for stent deployment type drugs conveyance according to claim 9 having at least one opening which circulation of a fluid is opening for free passage possible to said additional lumen to the end face side rather than said blockade balloon (122, 124) in a wall of said 1st catheter shaft.

[Claim 11]The catheter for stent deployment type drugs conveyance according to claim 1 characterized by comprising the following.

An inflation balloon (120) provided on said 2nd catheter shaft.

A lumen (112) for expansion provided in said 1st catheter shaft as circulation of a fluid was open for free passage possible to this inflation balloon (120).

[Claim 12]An inflation balloon (120) provided on said 2nd catheter shaft, A lumen (112) for expansion provided in said 1st catheter shaft as circulation of a fluid was open for free passage possible to this inflation balloon (120), The catheter for stent deployment type drugs conveyance according to claim 3, wherein a preparation and said inflation balloon (120) are arranged among said blockade balloons (122, 124).

[Claim 13]The catheter for stent deployment type drugs conveyance according to claim 9, wherein said additional lumen has a tapered shape tip.

[Claim 14]a tip part and a tip (134) -- and, A stent deployment means (120) attached to said tip part of a catheter shaft (110) which has a end face, and; this catheter shaft (110); As opposed to said catheter shaft (110). The 1st blockade balloon (122) attached to the tip side position rather than said stent deployment means (120); The 2nd blockade balloon (124) and; which

were attached to the end face side position rather than said stent deployment means (120) to said catheter shaft (110) are provided, Further in at least one [said stent deployment means (120) and] between of said blockade balloons (122, 124) said catheter shaft (110), At least one port (130) for drugs conveyance established in said tip part of said catheter shaft (110), at least one which circulation of a fluid opened for free passage possible to said balloon for a blockade (122, 124) -- swelling -- business -- with a lumen (118) and at least one lumen (114) for drugs conveyance which circulation of a fluid opened for free passage possible to said port (130) for drugs conveyance. Have a lumen (116) for guidewires provided in said tip part of said catheter shaft (110), and said lumen (116) for guidewires, The 1st opening that carries out an opening to the exterior of said catheter shaft (110) in said tip (134) of said catheter shaft (110), It reaches, In said tip part which is a end face side and is located in the tip side more nearly substantially than said base end of said catheter shaft (110) rather than said 2nd blockade balloon (124) of said catheter shafts (110). Have the 2nd opening (132) that carries out an opening to the exterior of said catheter shaft (110), and by this a guidewire (136), A catheter for stent deployment type drugs conveyance being able to enter in said catheter shaft (110) through said 1st opening, and being able to come out of said catheter shaft through said 2nd opening (132).

[Claim 15]The catheter for stent deployment type drugs conveyance according to claim 14, wherein said catheter shaft (110) is really a thing.

[Claim 16]A catheter for stent deployment type drugs conveyance characterized by comprising the following.

An inflation balloon (412) and; which were attached to said tip part of a catheter shaft (401) provided with a tip part, a tip, and a end face and; this catheter shaft are provided, Have said inflation balloon and an outer layer (430) and a inner layer (420) said inner layer (420), Form an interior area near [said] the catheter shaft (401), and said outer layer (430) and a inner layer (420), The 1st lumen in which an external area is formed, said outer layer (430) has two or more openings (428), and circulation of a fluid opened said catheter shaft (401) for free passage possible to said outside area further.

The 2nd lumen that circulation of a fluid opened for free passage possible to said inner area. The 3rd lumen provided in said tip part of said catheter shaft in order to accommodate a guidewire (418).

The 1st opening that carries out the opening of a preparation and said 3rd lumen to the exterior of said catheter shaft (401) in said tip (419) of said catheter shaft (401), It reaches, In said tip part which is a end face side and is located in the tip side more nearly substantially than said base end of said catheter shaft (401) rather than said inflation balloon (412) of said catheter shafts (401). Have the 2nd opening (417) that carries out an opening to the exterior of said catheter shaft (401), and by this said guidewire (418), It can enter in said catheter shaft

through said 1st opening, and can come out of said catheter shaft through said 2nd opening (417), and is a stent deployment means (412) in said tip part of said catheter shaft (401).

[Claim 17]The catheter for stent deployment type drugs conveyance according to claim 16, wherein said 1st lumen is constituted so that drugs can be conveyed, and said 2nd lumen is constituted so that a fluid for expansion can be conveyed.

[Claim 18]A balloon (412) for drugs conveyance and; which were attached to said tip part of a catheter shaft (401) provided with a tip part, a tip, and a end face and; this catheter shaft (401) are provided, Have said balloon (412) for drugs conveyance, and two or more ports (428) which penetrate this balloon and extend said catheter shaft (401), At least one lumen for conveyance which circulation of a fluid opened for free passage possible to said balloon (412) for drugs conveyance, And in order to accommodate a guidewire (418), have a lumen (406) provided in said tip part of said catheter shaft, and this lumen (406), The 1st opening that carries out an opening to the exterior of said catheter shaft in said tip (419) of said catheter shaft (401), It reaches, In said tip part which is a end face side and is located in the tip side more nearly substantially than said end face of said catheter shaft (401) rather than said balloon (412) for drugs conveyance of said catheter shafts (401). Have the 2nd opening (417) that carries out an opening to the exterior of said catheter shaft (401), and by this said guidewire (418), It can enter in said catheter shaft (401) through said 1st opening, A catheter for stent deployment type drugs conveyance, wherein it can come out of said catheter shaft (401) through said 2nd opening and a stent deployment means (412) is formed in said tip part of said catheter shaft (401).

[Claim 19]The catheter for stent deployment type drugs conveyance possessing a lumen for inflow according to claim 18.

[Claim 20]The catheter for stent deployment type drugs conveyance according to claim 19, wherein it went over said lumen for inflow and it has extended by said end face of said catheter shaft (401) from said tip of said catheter shaft (401).

[Claim 21]Said lumen for inflow from said tip (419) of said catheter shaft (401), Migrate even to a terminal point by the side of a end face, have extended rather than said balloon (412) for drugs conveyance, and said catheter shaft (401), While being located near [said] the terminal point of said lumen for inflow, so that blood can enter in said lumen for inflow, The catheter for stent deployment type drugs conveyance according to claim 19 provided with at least one port which penetrates said catheter shaft (401) and extends so that it may be open for free passage to said lumen for inflow.

[Claim 22]The catheter for stent deployment type drugs conveyance according to claim 21, wherein said lumen for inflow has a tapered shape tip.

[Translation done.]

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention]This invention relates to the catheter for balloon expansion type drugs conveyance, and the catheter for stent deployment type drugs conveyance, and is provided with the lumen for guidewires which carries out a termination into a catheter shaft, and the opening for taking out a guidewire from a catheter shaft.

[0002]

[Description of the Prior Art]A percutaneous transluminal arterioplasty ("PTA") and the percutaneous transluminal coronary-arteries plasty ("PTCA") expand an inflation balloon, in order to carry forward an inflation balloon to a strangulation part through a blood circulatory system and to open a barrier, and they are the usual method of operation nowadays. However, in about 1/3 of such an operation, the restenosis occurs and the further extended operation is needed.

[0003]Various drugs which may reduce the restenosis are applicable to a strangulation part. For example, an anti-thrombolysis agent like heparin can prevent a blockade. The thrombogen formation can cause various phenomena which may bring about the restenosis. An anti-growth agent like dexamethasone can prevent movement and growth of smooth muscle cells.

[0004]Various methods are proposed in order to convey such drugs effectively to an extended part. For example, the catheter which equipped Mr. Wolinsky's U.S. Pat. No. 5,087,244 with the light-gage flexible balloon in which two or more stomata were formed is indicated. After completion of an angioplasty, such a balloon is carried forward to an extended part, and expands with heparin or other drugs. Drugs let a stoma pass and are emitted from the inflation balloon in contact with an arterial wall.

[0005]The catheter provided with the conduit tube for drugs conveyance is indicated by Mr. Wolinsky's U.S. Pat. No. 4,824,436 and U.S. Pat. No. 4,636,195. The conduit tube for drugs

conveyance is provided among the blockade balloons of a couple. The embodiment by which the inflation balloon which makes possible the both sides of the expansion which uses the same catheter, and drugs conveyance was provided among the blockade balloons of a couple is indicated.

[0006]Other objects for expansion and the catheter for drugs conveyance are indicated by U.S. Pat. No. 4,994,033 of Shockey Mr. others. In this case, the double layer balloon in which two or more stomata were formed in the outer layer is provided. Drugs are introduced between two layers and the fluid for expansion is introduced into the inside of a balloon. While strangulation expands, drugs are directly applied to the extended organization by the pressure of the fluid for expansion.

[0007]

[Problem(s) to be Solved by the Invention]Typically, the object for drugs conveyance and the catheter for expansion are carried forward even to an extended part along with the guidewire accommodated in the lumen for guidewires which penetrated the whole shaft of the catheter and has extended. For the frictional force between a guidewire and a catheter, advance and removal of a catheter are difficult and time has required them.

[0008]In addition, when the whole catheter has covered the guidewire, to insert or exchange wires for a wrap catheter, the guidewire needs to project only length longer than the length of a catheter from the patient's body. The portion which length is about 300 cm and such a guidewire has in the outside of the body is about 230 cm. Otherwise, a guidewire cannot be fixed and arrangement [/ near the obstacle] cannot be maintained. It can replace with such a long guidewire and an exchange wire can be connected to the portion in the outside of the body of the guidewires at the time of exchange of a catheter. An exchange wire requires that length should be at least 180 cm. In the case of which, in order to deal with a long wire, at the time of operation, an additional operator is required. Even though an additional operator is needed, operation of the catheter at the time of exchange is inconvenient. Therefore, the length and expense of an operation will increase unnecessarily.

[0009]

[Means for Solving the Problem]At least one port for drugs conveyance in which it is located a tip and near this tip in an embodiment with this invention, And a catheter for drugs conveyance possessing a catheter shaft provided with at least one lumen for drugs conveyance for supplying drugs to this port for drugs conveyance is proposed. A catheter shaft is further provided with a lumen for guidewires which migrates even to a terminal point from a tip of a catheter shaft, and extends in a catheter shaft. A terminal point is arranged rather than a port for drugs conveyance at the end face side, and an opening for taking out a guidewire from a catheter shaft is formed near the terminal point. Therefore, a catheter shaft is only a wrap in a part of mere guidewire which extends over the outside of the body, and needs neither a long

guidewire nor an exchange wire. Preferably, a blockade balloon is provided in order to isolate a drugs transportation area. It is preferred that an additional lumen for inflow is provided. As for a tip of a lumen for inflow, being considered as tapered shape is preferred.

[0010]In other embodiments of this invention, a catheter for expanded type drugs conveyance possessing a catheter shaft provided with a tip part, a tip, and a end face is proposed. An inflation balloon is attached to a tip part of a catheter shaft. The 1st blockade balloon is attached to the tip side position rather than an inflation balloon to a catheter shaft, and the 2nd blockade balloon is attached to the end face side position rather than an inflation balloon to a catheter shaft. In between [at least one] of an inflation balloon and the blockade balloons, a catheter shaft equips a tip part of a catheter shaft with at least one port for drugs conveyance further. At least one lumen for expansion which circulation of a fluid opened for free passage possible to a balloon for expansion is provided. at least one which circulation of a fluid opened for free passage possible to a balloon for a blockade -- swelling -- business -- a lumen is provided. At least one lumen for drugs conveyance which circulation of a fluid opened for free passage possible to a port for drugs conveyance is provided similarly.

[0011]A lumen for guidewires is provided in a tip part of a catheter shaft. The 1st opening that carries out the opening of the lumen for guidewires to the exterior of a catheter shaft in a tip of a catheter shaft, And it has the 2nd opening that carries out an opening to the exterior of a catheter shaft in a tip part which is a end face side and is substantially located in the tip side rather than a base end of a catheter shaft rather than the 2nd blockade balloon of the catheter shafts. The guidewire can enter in a catheter shaft through the 1st opening, and can come out of a catheter shaft through the 2nd opening. As mentioned above, when the whole catheter shaft has not covered a guidewire, neither a long guidewire nor an exchange wire is required. A problem of a time lag for rearrangement and catheter displacement to a strangulation part after extension is avoided by the ability to carry out that it is also with the same catheter with both extension of a strangulation part, and drugs conveyance.

[0012]In embodiment of a catheter for expanded type drugs conveyance by this invention another again, an inflation balloon attached to a tip part of a catheter shaft has an outer layer and a inner layer. A inner layer forms an interior area near the catheter shaft, and an outer layer and a inner layer form an external area. An outer layer has two or more openings. Circulation of a fluid is opening the 1st lumen for free passage possible to an outside area, and circulation of a fluid is opening the 2nd lumen for free passage possible to an inner area. The 3rd lumen for accommodating a guidewire is provided in a tip part of a catheter shaft. The 1st opening that carries out the opening of the 3rd lumen to the exterior of a catheter shaft in a tip of a catheter shaft, And it has the 2nd opening that carries out an opening to the exterior of a catheter shaft in a tip part which is a end face side and is substantially located in the tip side rather than a base end of a catheter shaft rather than an inflation balloon of the catheter shafts.

The guidewire can enter in a catheter shaft through the 1st opening, and can come out of a catheter shaft through the 2nd opening.

[0013]In another embodiment of this invention, a balloon for drugs conveyance with two or more ports is attached to a tip part of a catheter shaft. A catheter shaft is provided with a lumen provided in a tip part of a catheter shaft in order to accommodate further at least one lumen for conveyance which circulation of a fluid opened for free passage possible to a balloon for drugs conveyance, and a guidewire. The 1st opening that carries out the opening of the lumen for guidewires to the exterior of a catheter shaft in a tip of a catheter shaft, And it has the 2nd opening that carries out an opening to the exterior of a catheter shaft in a tip part which is a end face side and is substantially located in the tip side rather than a base end of a catheter shaft rather than a balloon for drugs conveyance of the catheter shafts. Also in this case, the guidewire can enter in a catheter shaft through the 1st opening, and can come out of a catheter shaft through the 2nd opening. It is preferred that a lumen for inflow is provided. As for a lumen for inflow, it is preferred to have a tapered shape tip.

[0014]In further embodiment of this invention, a drugs transportation means is combined with both sides of space expansion and arrangement of stent which can be balloon expanded in the same catheter shaft.

[0015]

[Embodiment of the Invention]Drawing 1 is a figure showing the catheter for drugs conveyance by one embodiment of this invention, about the tip part of the catheter, is expanded and is illustrated in the section. Drawing 2 is a sectional view showing the tip part of the catheter shown in drawing 1 along two to 2 line of drawing 1. Drawing 3 is a sectional view in which 90 degrees' rotating and showing the tip part of the catheter shown in drawing 1. Drawing 4 is a sectional view showing the tip part of the catheter shown in drawing 3 along four to 4 line of drawing 3. Drawing 5 is a sectional view showing the base end of the catheter shown in drawing 1 along five to 5 line of drawing 1. Drawing 6 is a top view showing the catheter shown in drawing 3 with the blockade balloon which expanded. Drawing 7 is a figure showing the tip part of a 2nd embodiment of this invention in a flat surface and a section. Drawing 8 is a figure showing the tip part of a 3rd embodiment of this invention in a flat surface and a section.

Drawing 9 is a figure showing a 4th embodiment of this invention in a flat surface and a section. Drawing 10 - drawing 13 are the figures showing a 5th embodiment of this invention.

[0016]Drawing 1 - drawing 6 show one embodiment of the catheter 10 for drugs conveyance by this invention. In drawing 1, the tip part of the catheter 10 is expanded and is shown by the section. The catheter 10 is provided with the catheter shaft 12. Preferably, the two blockade balloons 22 and 24 are attached to the tip part of the catheter shaft 12. The 1st lumen 14 that migrates even to the about 24 blockade balloon terminal point 14a from the tip 26 of the catheter shaft 12, and extends is formed so that the guidewire 28 may be received. The

opening 30 is formed in the wall of the catheter shaft 12 [near the terminal point 14a]. Preferably, the 1st lumen 14 is arranged near the edge part of the catheter shaft 12. The guidewire 28 can pass along the opening 31 in the tip part 26 of the catheter shaft 12, and can enter into the 1st lumen 14 of the catheter shaft 12, and can come out of the opening 30. Substantially, the opening 30 is located in the tip side of the base end of the catheter 10. The diameter of the 1st lumen can be about 0.022 inch (0.56 mm). At the time of use, the tip part of the guidewire 28 is projected from the tip of the lumen 14, as shown in drawing 1. As for the distance between the tip of a catheter, and the opening 30, it is preferred that it is about 5-25 cm. Although shorter longer or length is possible for the total length of the catheter 10 for drugs conveyance, it can be begun from 120-160 cm. It is not necessary to use too long a wire according to the guidewire 28 being able to come out of the catheter shaft 12 through the opening 30. It is not necessary to use an exchange wire. When removing from the body, a part of mere guidewire which extends over the outside of the body is because it is covered by the catheter 10. Therefore, when the catheter 10 of this invention is inserted into the body or is removed, sufficient allowance for being held in a prescribed position exists in a guidewire. In the catheter 10 by this invention, the guidewire 28 only projects about 75 cm from the body.

[0017]Preferably, the 2nd lumen 16 migrated even to the about 24 blockade balloon terminal point 16a from the tip 26 of the catheter shaft 12 again, and has extended. The diameter of the 2nd lumen can be about 0.013 inch (0.33 mm). Preferably, the wall of the catheter shaft 12 is penetrated and two or more ports 32 are formed so that it may be open for free passage to the 2nd lumen 16. Two or more ports 32 can enable active inflow of the blood which lets a lumen pass so that it may explain further below. It is preferred that the port 32 of circular or an ellipse form a diameter or whose length is 2-20 about 0.003-0.020 inch (0.076-0.51 mm) pieces, respectively is formed. The three openings 32 for inflow are formed in this embodiment. The port 30a which is open for free passage to the 1st lumen 14 for enabling similarly inflow of the blood which lets the 1st lumen 14 pass can be formed between the end face blockade balloon 24 and the opening 30. As for the tip 16b of the 2nd lumen 16, as shown in drawing 1, it is preferred that it is tapered shape. The opening in the tip 16b being able to become difficult to be seen, mistaking to the 1st lumen 14 by this, at the time of use, and inserting the guidewire 28 into the 2nd lumen 16 is prevented. Active inflow of the perfluorochemical known from blood or the former or recombination nature hemoglobin is enabled so that it replaces with such composition, and the lumen 16 may be made to extend covering the whole length of the catheter shaft 12 and this may explain it below.

[0018]Drawing 2 is a sectional view which meets two to 2 line of drawing 1, and shows the 3rd lumen 18 and the 4th lumen 20 to the 1st lumen 14 and the 2nd lumen 16, the port 32, and the pan. The 3rd lumen 18 and the 4th lumen 20 are explained with reference to drawing 3.

[0019]Drawing 3 is a sectional view in which 90 degrees' rotating and showing the tip part of

the catheter 10. The graphic display abbreviation of the guidewire 28 is carried out. The 3rd lumen 18 is shown in the figure. This 3rd lumen 18 is for letting the port 34 which penetrates the catheter shaft 12 pass to the blockade balloons 22 and 24, and supplying the fluid for expansion. Preferably, in order to blow up the both sides of the balloons 22 and 24, the single lumen 18 is used. The diameter of the 3rd lumen 18 can be set to about 0.010 (0.25 mm). Similarly, two or more lumina isolated to each balloons 22 and 24 can also be provided.

[0020]The 4th lumen 20 for conveying drugs is illustrated again. Among blockade balloons, at least one port 36 for drugs conveyance penetrates the catheter shaft 12, and it is provided so that it may be open for free passage to the 4th lumen 20. The diameter of the 4th lumen 20 can be set to about 0.010 (0.25 mm). In order to make conveyance of suitable drugs to an expansion part into a positive thing, it is preferred that the port 36 of circular or an ellipse form a diameter or whose length is 2-20 about 0.003-0.020 inch (0.076-0.51 mm) pieces, respectively is formed. In drawing 3, the number of such ports is three. The drugs of arbitrary requests can be conveyed by the 4th lumen 20 to an expansion part. Drawing 4 is a sectional view by four to 4 line of drawing 3 of the catheter shaft 12, and the arrangement situation of two or more lumina which can be set to drawing 3 is shown. The additional lumen for drugs conveyance can be provided.

[0021]As for the blockade balloons 22 and 24, at the time of drugs conveyance, it is preferred that an expansion part can be isolated. The blockade balloons 22 and 24 maintain drugs near [where it already swelled of the arterial walls] the portion. Thereby, absorption and validity of drugs improve. Drawing 6 is a top view of the catheter 10 of direction of drawing 3, and the blockade balloons 22 and 24 blown up at the time of drugs conveyance just before drugs conveyance are shown. The port 36 for drugs conveyance is also illustrated by the guidewire 28 and pan which have come out of the opening 30 and the opening 30. The opening 32 for inflow is located in the other side of a catheter in this figure.

[0022]It can replace with the integral-type catheter shaft 12 provided with two or more lumina, and the catheter shaft 12 can be provided with two or more tubes pasted up appropriately mutually. In addition, it can expand in drawing 6 and the tip part of the shown catheter shaft 12 can be formed from a material softer than other portions of a shaft. If formed from material with a soft tip part, the operativity which lets a blood circulatory system pass can be raised. On the other hand, pushing nature can be made good if the remaining portion of the shaft is formed from a harder material. These two portions can only be combined with heat adhesion or adhesives which is known in conventional technology. A suitable material is mentioned later. the wire (not shown) of the product made from the product made from stainless steel, or tungsten in order to raise the hardness and pushing nature of the catheter 10 further -- it can provide in the base end of the catheter shaft 12.

[0023]If drawing 1 is referred to again, the two tubes 72 and 74 connected to the catheter shaft

12 are formed in the base end of the catheter 10. One tube is a thing for supply of the fluid for expansion, and is connected to the 3rd lumen 18. The tube of another side is a thing for supply of drugs, and is connected to the 4th lumen 20. The hub 78 is connected with each tube. A syringe can be used, in order to let the tubes 72 and 74 pass and to supply the fluid for expansion to the blockade balloons 22 and 24, and in order to supply the drugs of arbitrary requests. When it is applied for active inflow of the catheter 10 and the 2nd lumen 16 has extended even in the base end of the catheter shaft 12, the 3rd tube (not shown) can be attached to the 2nd lumen 16. When the additional lumen is provided, an additional tube can be attached to the catheter shaft 12. Or Y adapter can be attached. Drawing 5 is a sectional view showing a catheter shaft along five to 5 line of drawing 1, and the 3rd lumen 18 and the 4th lumen 20 are shown.

[0024]As for the outer diameter of the catheter 10 and the blockade balloons 22 and 24 in the state where it became narrower, it is preferred not to exceed about 0.056 inch (1.42 mm). Thereby, it can be used with 7 or 8 French guiding catheter (7 or 8 French guiding catheter).

[0025]At the place 80, the diameter of the base end 52 of an inside catheter shaft is about expanded even in outer diameter of about 0.140 inch (3.56 mm) so that the tubes 72 and 74 may be received. The tubes 72 and 74 of each other are held with the heat-shrinkable tubing 82. The tubes 72 and 74 are connected to the catheter shaft by heat adhesion or adhesives.

[0026]The tip 26 of the 1st lumen 14 is preferably provided with the elastic chip 96 which has a softer material as compared with the material of the catheter shaft 12. When a body tissue is contacted, the chip 96 spreads or it turns at it. Passage of the catheter which passes along a blood circulatory system is made easy by this, and it is useful for prevention of damage to an organization. The chip 96 can be formed from the ultra low density polyethylene 4603 by Dow Chemical Corporation. This material has a melt flow index (ASTM D-1238) of 0.7-0.9g / 10min, and the density (ASTM D-792) of 0.9030-0.9070g/cc in 190 **. The chip 96 can be made into nylon or the polyamide copolymer like PEBA 25D by Elf Atochem Deutschland GmbH. This material The tensile strength of a minimum of 4950 psi (ASTM D-638), It has a minimum of 640% of elongation (ASTM-638), a flexibility factor (ASTM D-790) of a minimum of 2100 psi, a durometer (ASTM D-2240) of 25D**4D, and the melting point (ASTM D-3418) of 142 ** - 153 **. The chip 96 can be connected to the catheter shaft 12 by adhesives or heat adhesion.

[0027]For position observation of the catheter by PTA or the X-ray fluorography at the time of a PCTA operation as the opaque marker 98 is known from the former, for example to the radiation made from gold or tantalum, It is preferred to be provided in the blockade balloon 22 and 24 at the catheter shaft 12, as shown in drawing 1. Such a marker can also be provided in the end face of other arrangement 32, for example, the port of the method of the last.

[0028]The catheter shaft 12 and the blockade balloons 22 and 24 are preferably coated with a charge of a sliding material like silicon, acrylicimide, or hydrophilic polyurethane coating.

Thereby, passage of the catheter 10 for drugs conveyance by this invention which passes along a guiding catheter is made easy as known from the former.

[0029]The arbitrary materials for a catheter with a suitable catheter shaft. For example, it can form from linearity low density polyethylene or high density polyethylene, nylon, polyamide, a polyamide copolymer, polyurethane, polypropylene, a polyester copolymer, silicone rubber, or other non-thrombogen formation materials. The product made from stainless steel, or Nitinol (Nitinol) The metal tube made from an available nickel titanium alloy can also be used, for example from Raychem Corporation in a similar manner [of make].

[0030]Suitable linearity low density polyethylene is Dowlex2038 by Dow Chemical Company. This material has a melt flow index (ASTM D-1238) of 0.85-1.15g / 10min, and the density (ASTM D-792) of 0.9330-0.9370g/cc in 190 **. Usable high density polyethylene is LB 8320-00 by Quantum Chemical Corporation. This material has a melt flow index (ASTM D-1238) of 0.20-0.36g / 10min, and the density (D-1505) of a minimum of 0.9566g/cc in 190 **.

[0031]Usable nylon is Nylon 12 like L2101F Vestamed by Huls America Inc. This material has the relative viscosity (ISO 307) of 2.05-2.22, and a maximum of 0.10 water content (ASTM D-4109). Other usable nylon is PEBA 70D by Elf Atochem. This material The tensile strength of a minimum of 8300 psi (ASTM D-638), It has a minimum of 400% of elongation (ASTM D-638), a flexibility factor (ASTM D-790) of a minimum of 67,000 psi, a durometer (ASTM D-2240) of 69D**4D, and the melting point (ASTM D-3418) of 160 ** - 180 **.

[0032]Usable high density polyethylene is LM6007 by Quantum Chemical Corporation. This material has the following characteristics.

Tensile strength A minimum of 4400 psi (ASTMD-638)

it can set to a burst -- being extended -- % -- a minimum of 600% (ASTM D-638)

D coefficient 68**4.5 of a durometer (ASTM D-2240)

0.070 (REF) at 240 ** and 2160 g

Melt flow index (ASTM D-1238)

Flexibility factor in a room temperature A minimum of 220,000 psi (ASTM D-790, the technique B)

Vicat softening temperature, ** 125 ** (REF)

(ASTM D-1525)

[0033]When it is requested that the tip part of the catheter shaft 12 is softer than other portions of a shaft, usable suitable nylon is PEBA 63D by Elf Atochem. This material The tensile strength of a minimum of 8100 psi (ASTM D-638), It has a minimum of 300% of elongation (ASTMD-638), a flexibility factor (ASTM D-790) of a minimum of 49,000 psi, a durometer (ASTM D-2240) of 63D**4D, and the melting point (ASTM D-3418) of 160 ** - 180 **.

[0034]The catheter shaft 12 provided with the lumen of a desired number can be manufactured by the conventional extrusion process. In order to form the expanding part of the catheter shaft

12, a vamp extrusion process can be used as known in conventional technology. It can replace with the integral-type catheter shaft 12 with a lumen, and two or more individual tubes connected mutually can be used.

[0035]The elastic chip 96 can be attached to a catheter shaft by carrying out heat adhesion in a prescribed position by arranging the small tube of the charge of a chipped material on the tip of the catheter shaft 12. Similarly, adhesives can be used. The catheter shaft 12 will increase the charge of a tube material. In order to maintain the outer diameter of the catheter shaft 12 after arrangement of the tube of the charge of a chipped material smaller than about 0.056 inch (1.42 mm), In advance of attachment of the charge of a chipped material, only a suitable quantity "being able to shut (necked-down)" the tip part of a catheter shaft. [make able to decrease it or] In order to attach an elastic chip by heat adhesion, maintaining the lumina 14 and 16 to an opening state, an axis is inserted into each lumen. The tube of the charge of a chipped material can extend even to the field to which the tip blockade balloon 22 of the catheter shafts 12 is attached. In this case, all or some of balloons 22 can attach to the charge of a chipped material.

[0036]At the time of heat adhesion of the charge of a chipped material, the tip part of the 3rd lumen 18 and the 4th lumen 20 is blockaded. When it is required to blockade more portions of one of lumina, the small solid tube made from the same material as the catheter shaft 12 is inserted into the end face of the lumen, and heat adhesion is carried out after that in a prescribed position. Adhesives can be used similarly. The thing large more slightly than the diameter of said lumen of the outer diameter of a tube is preferred. An axis maintains other lumina to an opened condition. When the 3rd lumen 18 is not blockaded at the time of attachment of the elastic chip 96, it can blockade like the 4th lumen.

[0037]The seal of the base end of the 1st lumen 14 and the 2nd lumen 16 can be carried out similarly.

[0038]The blockade balloons 22 and 24 Nylon, polyamide, a polyamide copolymer, It can form from polyethylene, polyethylene terephthalate, a polyester elastomer, polyurethane, Kapton (Kraton), silicone, latex, or other arbitrary flexible non-thrombogen formation materials.

Although the blockade balloons 22 and 24 do not blow up a blood vessel wall when it swells, they carry out the seal of the blood vessel wall. A balloon can be used as the balloon by which could consider it as the tube which swells by expansion, or blow molding was carried out.

When balloon material has conformity to the catheter shaft 12, the blockade balloons 22 and 24 can be attached by heat adhesion art including laser adhesion. The device and method for carrying out laser adhesion of the balloon on a catheter are indicated by U.S. Pat. No.

5,267,959. This literature is incorporated here for reference. Adhesives can be used similarly. Nylon usable as the blockade balloons 22 and 24 is L25G Grilamid by EMS-Chemie AG. This material The melting point of 178 **, the density of 1.01 kg/dm^3 (DIN 53479), It has the tensile

strength (DIN 53455) of $40\text{N}/[\text{mm}]^2$, the elongation (DIN 53455) in 10% of burst, and the Shore (Shore)D hardness (DIN 53505) of 72.

[0039] After expansion is attained by the usual method, the catheter for drugs conveyance by a 1st embodiment of this invention can be used even for the treatment part by the PTA method or the PTCA method in order to convey drugs. An expansion catheter consists of a quick exchange format which is indicated by Mr. Bonzel's U.S. Pat. No. 4,762,129 preferably, for example. This literature is incorporated here for reference. Such a catheter is removed first. After that, the catheter 10 for drugs conveyance of this invention is introduced in a blood circulatory system, and is carried forward even to an expansion part via a guiding catheter along with the same guidewire that showed said expansion catheter even to the strangulation part. An exchange wire is not required at all and the guidewire needs to project only about 75 cm from the body. The tip of the 1st lumen 14 of the catheter 10 is inserted into a guidewire like the guidewire 28 shown in drawing 1. When a catheter advances along with a guidewire, the guidewire has come out of the opening 30 of the catheter 10. The catheter 10 continues being conveyed along with the portion located in the 1st lumen 14 of the guidewires, when moving forward even to an expansion part.

[0040] The progress condition of the catheter 10 is pursued by X-ray fluorography. When it arrives at an expansion part, it swells through the 3rd lumen 18 until the blockade balloons 22 and 24 carry out the seal of the arterial wall in contact with an arterial wall. When the openings 32 and 30a for inflow exist, it flows through the 2nd lumen 16 and the 1st lumen 14, and flows out of the tip part of the catheter 10, respectively. When it is constituted so that the catheter 10 can perform active inflow (.) Namely, when the 2nd lumen 16 has extended covering the whole length of the catheter shaft 12. Blood or a fault fluorine compound like Fluosol (registered trademark), and recombination nature hemoglobin can be poured in by a syringe via the tube 76 as known in conventional technology.

[0041] An anti-thrombolysis agent, an anti-growth agent, or drugs arbitrary type [other] can be poured in by a syringe here through the tube 72, the 4th lumen 20, and also the port 36 for drugs conveyance. One effective gestalt of drugs is the dexamethasone made to stick to the polylactic acid / polyglycolic acid particles of a diameter smaller than 100 microns substantially. Such particles stick to an arterial wall, or can penetrate an arterial wall. A particle surface can be processed with cell adsorptivity protein, in order to heighten the adsorption power of the particles to an arterial wall. Peptide based on usable arginine glycine aspartic acid is Peptide 2000 (registered trademark) by Telios Pharmaceuticals and Inc.

[0042] After continuing for desired time (typically about 20 seconds - 3 minutes) and applying drugs by a desired pressure, a blockade balloon is ***** (ed) and the catheter 10 for drugs conveyance is drawn out promptly and easily from a blood vessel.

[0043] Drawing 7 is a figure showing the tip part of a 2nd embodiment of this invention in a flat

surface and a section, and the catheter 100 which can perform both extension and drugs conveyance is shown. The catheter 100 is provided with the catheter shaft 110 which has the 1st lumen 112, the 2nd lumen 114, the 3rd lumen 116, and the 4th lumen 118. The inflation balloon 120 and the two blockade balloons 122 and 124 are attached to the catheter shaft 110. The free passage of the 1st lumen 112 and a fluid of the inflation balloon 120 is enabled through the opening 126. The free passage of the 4th lumen 118 and a fluid of both blockade balloons is similarly enabled through the opening 128. The wall of the catheter shaft 110 is penetrated in the 2nd lumen 114, the port 130 is established in it, it can let this port 130 pass, and medication to an expansion part can be performed. The additional lumen for drugs conveyance can be provided like the above. The additional lumen can provide a fluid to the blockade balloons 122 and 124 as opposed to the inflation balloon 120 similarly. The wall of the catheter shaft 110 is penetrated to the 3rd lumen 116, and the opening 132 is formed in it. The 3rd lumen 116 that penetrated the opening 133 in the tip 134 of the catheter 100, and has extended has accommodated the guidewire 136 which exists in this lumen 116 through the opening 132. an additional lumen (not shown) -- it may provide for active or passive inflow. The tip of such a lumen for inflow is preferably made into tapered shape as mentioned above. The above slide coating is applied to the inflation balloon 120 and the remaining portion of the catheter 100. As mentioned above, it can replace with the integral-type catheter shaft which has two or more lumina, and the catheter shaft 110 can consist of two or more tubes combined appropriately mutually.

[0044]The inflation balloon 120 can be made into the thing of the suitable arbitrary types for the PTA method and the PTCA method, and size. For example, the balloon 120 can be formed from polyethylene, polyethylene terephthalate, nylon, polyamide, a polyamide copolymer, polyurethane, or other arbitrary materials suitable as an inflation balloon. the balloon 120 -- adaptability and non-adaptability -- or -- half-- suppose that it is flexible. The inflation balloon 120 can be attached to the catheter shaft 110 with the heat adhesion including laser adhesion or ultrasonic bonding or adhesives as known in conventional technology. As for the balloon 120, it is preferred that it is the same material as the catheter shaft 110, or is a conformable material so that heat adhesion may be possible.

[0045]Low density polyethylene usable as the inflation balloon 120 is P.E.1031 by RexeneCorporation. In 190**0.2 **, this material The melt flow index of 0.4-1.4g / 10min (ASTM D-1238), It has the density (ASTM D-1505) of 0.93**0.02g/cc, and the melting point (ASTM D-3417, D-3418) of 104-140 **. Usable linearity low density polyethylene is Dowlex2247A LLPDE by Dow Chemical Corporation. In 190 **/2.16 kg, this material The melt index of 2.0-2.6g / 10min (ASTM D-1238), It has the density (ASTM D-1505) of 0.9150-0.9190g/cc, and the melting point (D-3417, D-3418 (REF)) of 122-125 **.

[0046]The material mentioned above in relation to a 1st embodiment is suitable for other

corresponding members in this embodiment. The radiation opaque marker 138 is established under the blockade balloons 122 and 124 under the inflation balloon 120 like a 1st embodiment again at the catheter shaft 110. The structure of the end face of the catheter 100 is intrinsically [as the end face of the catheter 10 shown in drawing 1] the same. However, only the point that the 3rd tube for supplying the fluid for expansion to the inflation balloon 120 through the 1st lumen 112 is attached is different from the end face of the catheter shaft 110. Y adapter can be used again as known in conventional technology.

[0047]At the time of use, the catheter 100 of this embodiment is inserted in a guidewire like the guidewire 136 already advanced even to the strangulation part by the guiding catheter as known in conventional technology. It invaded through the opening 134 in the catheter 100, and has come out from the 3rd lumen 116 through the opening 132. As mentioned above, when some catheters 100 are carrying out friction engagement with the guidewire, while being able to follow a catheter to a strangulation part easily and promptly, the guidewire to be used is short and ends. When arranged properly, the inflation balloon 120 can swell by the conventional method, in order to open a strangulation part. Then, it is made to become narrower about the inflation balloon 120, and the blockade balloons 122 and 124 can be blown up as mentioned above. The drugs of arbitrary requests can be supplied through the 2nd lumen 114 after that. By the ability to perform both extension and drugs conveyance as it is also with the same catheter, in this embodiment, time required to draw out the catheter for expansion and insert the catheter for drugs conveyance of a different body further can be saved, and operation time can be shortened. In addition, in this embodiment, the problem of the exact rearrangement to the expansion part for the optimal location and allocation of the catheter for drugs conveyance can be eased.

[0048]In a 3rd embodiment of this invention, both extension of a strangulation part and drugs conveyance to an extended part can be performed as, as for the catheter 200, the same inflation balloon is also. Drawing 8 is a figure showing the tip part of such a catheter 200 in a flat surface and a section, and the state where the inflation balloon expanded is shown. The catheter 200 is provided with the catheter shaft 210, the 1st lumen 212, the 2nd lumen 214, and the 3rd lumen 216. The 2nd lumen 214 has accommodated the guidewire 218 through the opening 219. In order to form the exit of the guidewire 218, the catheter shaft 210 is penetrated in the 2nd lumen 214, and the opening 217 is formed in it. It can replace with the integral-type catheter shaft which has two or more lumina, and the catheter shaft 210 can consist of two or more tubes combined appropriately mutually.

[0049]The balloon part of the catheter 200 is provided with the outside balloon 220 and the inner balloon 230. The 2nd lumen 214 inserted in the inside of the inner balloon 230, and has extended. The tip of the outside balloon 220 is pasted up with heat or adhesives to the tip of the inner balloon 230. On the other hand, at the place 240, the tip of the inner balloon 230 is

pasted up with heat or adhesives to the outside surface of the 2nd lumen 214. Both the end faces of the outside balloon 220 and the inner balloon 230, To the catheter shaft 210, it is in the state in which the middle field of an outside balloon and an inner balloon is carrying out fluid communicating to the 1st lumen 212, and has pasted up with heat or adhesives in the state where the inside of the inner balloon 230 is carrying out fluid communicating to the 3rd lumen 216. The fluid for expansion is supplied through the 3rd lumen 216, and drugs are supplied through the 1st lumen 212. In order that two or more micropores 280 may emit drugs from a balloon, the wall of the outside balloon 220 is penetrated and it is formed. Such a hole can be 0.01 micron - 0.1 mm. When the outer layer of the balloon 220 is provided with polyethylene terephthalate, nylon, or biaxial orientation plastic material like a polyester elastomer, the micropore 280 can be formed using high-precision laser.

[0050]At the time of use, the guidewire 218 is advanced to the fault part with which it should deal via a guide catheter by the conventional method. The tip of the 2nd lumen 214 is attached over the base end of the guidewire 218. The guidewire has come out from the catheter 200 through the opening 217 like both the above-mentioned embodiments. The catheter 200 continues advance along with the portion in the 2nd lumen 214 of the guidewires until it arrives at the fault part where it should deal with a balloon part. In drawing 8, the inner layer 230 and the outer layer 220 of the balloon part are illustrated by the expanding state, however when these layers move forward to a strangulation part, they are in the state where it stuck to the outside surface of the lumen 214.

[0051]If the tip part of the catheter 200 is appropriately arranged using the radiation opaque marker band 242, selected drugs will let the 1st lumen 212 pass, and will be introduced into the staging area of outside balloon 220 and the inside balloon 230. Although pouring of drugs brings about some extension of the outside balloon 220, typically, the pressure that drugs are poured in is smaller than the pressure that the quantity of drugs will be substantially emitted from the micropore 280. In order to perform both drugs conveyance and extension simultaneously next, the fluid for expansion lets the 3rd lumen 216 pass, and is poured in inside the inner balloon 230. If a pressure increases and 7-8 atmospheres will be reached typically, the inner layer 230 of a balloon will swell even to a predetermined maximum diameter. And by swelling in this way, to the fault part with which it deals that it is also with special drugs, it can let the port 280 pass and drugs can be sprinkled effectively. While the pressure which acts to a fault part is brought about again and drugs apply by expansion of the inner balloon 230, forcing to a blood vessel wall can be performed.

[0052]Use of the balloon for conveyance of the drugs to the expansion part by the catheter for drugs conveyance of this invention is shown in a 4th embodiment of drawing 9. The catheter 300 is provided with the balloon 312 for drugs conveyance attached by heat or adhesives to the catheter shaft 310 as mentioned above. The balloon 312 is shown by the expanding state

in drawing 9. Two or more ports 314 for drugs conveyance are formed over the balloon 312. The balloon 312 lets the port 318 which penetrates the wall of the catheter shaft 310 pass, and is carrying out fluid communicating to the lumen 316 for drugs conveyance. The additional lumen for drugs conveyance can be provided again. The lumen 320 for guidewires penetrates the tip 322, and is provided in the tip part of the catheter shaft 310. The termination of the lumen 320 for guidewires is carried out to the end face side of the balloon 312 for drugs conveyance of the tip parts of the catheter shaft 310. The opening 324 which is open for free passage to the lumen 320 for guidewires is formed in the wall of the catheter shaft 310. The guidewire 326 can be inserted through the opening 328 in the tip 322 of the catheter shaft 310, and can be taken out through the opening 324.

[0053]It is preferred to form the lumen 330 for inflow in which the tapered shape end 330a was formed. As mentioned above, this lumen can extend covering the whole length of the catheter shaft 310 so that active inflow may be enabled. It can replace with this and the termination of this lumen can be carried out to the end face side of the balloon 312 for drugs conveyance. In that case, in order to enable active inflow, like a 1st embodiment, the wall of the catheter shaft 310 can be penetrated and two or more openings (not shown) can be provided. It can replace with the integral-type catheter shaft provided with two or more lumina, and the catheter shaft 310 can consist of two or more tubes pasted up appropriately mutually.

[0054]A 5th embodiment of the invention in this application combines a space expansion function and a local drugs carrying function with the balloon extension type stent. The non-expanding state and the expanding state are shown in drawing 10, 11 and drawing 12, and 13, respectively. The catheter 400 is provided with the object for double-wall type expansion and the balloon 412 for drugs conveyance which it was welded or were pasted up on the catheter shaft 401 like ****, the 1st lumen 405, the 2nd lumen 406, and the 3rd lumen 407. The 2nd lumen 406 has received the guidewire 418 through the opening 419. To the 2nd lumen 406, the catheter shaft 401 is penetrated and the opening 417 is formed. This opening 417 can make the exit for the guidewire 418. It can replace with the integral-type catheter shaft in which two or more lumina are provided, and the catheter shaft 401 can also consist of two or more tubes pasted up mutually again.

[0055]The double-wall balloon 412 is the same as the double-wall balloon in a 3rd embodiment of this invention. The stent 440 which can be balloon expanded is attached to the double-wall balloon. Means of attachment can be performed by other arbitrary methods of demounting the stent from a double-wall balloon at the time of engagement, and balloon expansion and stent deployment.

[0056]At the time of use, the guidewire 418 is advanced to the fault part with which it should deal via a guide catheter by the conventional method. The tip 419 of the 2nd lumen 406 is attached over the base end of the guidewire 418. The guidewire has come out from the

catheter 400 through the opening 417 like both the above-mentioned embodiments. The catheter 400 continues advance along with the portion in the 2nd lumen 406 of the guidewires until it arrives at the fault part where it should deal with a balloon part. In drawing 10 - drawing 13, the inner layer 430 and the outer layer 420 of the balloon part are illustrated by the expanding state, however when these layers move forward to a strangulation part, they are in the state where it stuck to the outside surface of the lumen 419.

[0057]If the tip part of the catheter 400 is appropriately arranged using the radiation opaque marker band 442, selected drugs will let the 3rd lumen 407 pass, and will be introduced into the staging area of outside balloon 430 and the inside balloon 420. Although pouring of drugs brings about some extension of the outside balloon 430, typically, the pressure that drugs are poured in is smaller than the pressure that the quantity of drugs will be substantially emitted from the micropore 428. In order to perform drugs conveyance, extension of strangulation, and arrangement of the stent simultaneously next, the fluid for expansion lets the 1st lumen 405 pass, and is poured in inside [421] an inner balloon. If a pressure increases and 7-8 atmospheres will be reached typically, the inner layer 420 of a balloon will swell even to a predetermined maximum diameter. And while being able to sprinkle drugs effectively to the fault part with which it deals that it is also with special drugs by swelling in this way, the stent is expanded and the stent can be pushed to a blood vessel wall. Drugs are emitted from the hole of an outside balloon and permeate through the lattice of the stent.

[0058]In the catheter for drugs conveyance and the catheter for expanded type drugs conveyance by this invention, advance and drawing out of a quick and easy catheter are possible, and, therefore, the time which an operation takes can be shortened. A required staff and device can be omitted and operation cost can be reduced.

[0059]In the above, although the desirable embodiment of this invention has been described, the above-mentioned embodiment does not restrict the range of this invention, and the range of this invention is defined by the claim.

[Translation done.]

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TECHNICAL FIELD

[Field of the Invention]This invention relates to the catheter for balloon expansion type drugs conveyance, and the catheter for stent deployment type drugs conveyance, and is provided with the lumen for guidewires which carries out a termination into a catheter shaft, and the opening for taking out a guidewire from a catheter shaft.

[Translation done.]

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PRIOR ART

[Description of the Prior Art]A percutaneous transluminal arterioplasty ("PTA") and the percutaneous transluminal coronary-arteries plasty ("PTCA") expand an inflation balloon, in order to carry forward an inflation balloon to a strangulation part through a blood circulatory system and to open a barrier, and they are the usual method of operation nowadays. However, in about 1/3 of such an operation, the restenosis occurs and the further extended operation is needed.

[0003]Various drugs which may reduce the restenosis are applicable to a strangulation part. For example, an anti-thrombolysis agent like heparin can prevent a blockade. The thrombogen formation can cause various phenomena which may bring about the restenosis. An anti-growth agent like dexamethasone can prevent movement and growth of smooth muscle cells.

[0004]Various methods are proposed in order to convey such drugs effectively to an extended part. For example, the catheter which equipped Mr. Wolinsky's U.S. Pat. No. 5,087,244 with the light-gage flexible balloon in which two or more stomata were formed is indicated. After completion of an angioplasty, such a balloon is carried forward to an extended part, and expands with heparin or other drugs. Drugs let a stoma pass and are emitted from the inflation balloon in contact with an arterial wall.

[0005]The catheter provided with the conduit tube for drugs conveyance is indicated by Mr. Wolinsky's U.S. Pat. No. 4,824,436 and U.S. Pat. No. 4,636,195. The conduit tube for drugs conveyance is provided among the blockade balloons of a couple. The embodiment by which the inflation balloon which makes possible the both sides of the expansion which uses the same catheter, and drugs conveyance was provided among the blockade balloons of a couple is indicated.

[0006]Other objects for expansion and the catheter for drugs conveyance are indicated by U.S. Pat. No. 4,994,033 of Shockey Mr. others. In this case, the double layer balloon in which two or more stomata were formed in the outer layer is provided. Drugs are introduced between two

layers and the fluid for expansion is introduced into the inside of a balloon. While strangulation expands, drugs are directly applied to the extended organization by the pressure of the fluid for expansion.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]Typically, the object for drugs conveyance and the catheter for expansion are carried forward even to an extended part along with the guidewire accommodated in the lumen for guidewires which penetrated the whole shaft of the catheter and has extended. For the frictional force between a guidewire and a catheter, advance and removal of a catheter are difficult and time has required them.

[0008]In addition, when the whole catheter has covered the guidewire, to insert or exchange wires for a wrap catheter, the guidewire needs to project only length longer than the length of a catheter from the patient's body. The portion which length is about 300 cm and such a guidewire has in the outside of the body is about 230 cm. Otherwise, a guidewire cannot be fixed and arrangement [/ near the obstacle] cannot be maintained. It can replace with such a long guidewire and an exchange wire can be connected to the portion in the outside of the body of the guidewires at the time of exchange of a catheter. An exchange wire requires that length should be at least 180 cm. In the case of which, in order to deal with a long wire, at the time of operation, an additional operator is required. Even though an additional operator is needed, operation of the catheter at the time of exchange is inconvenient. Therefore, the length and expense of an operation will increase unnecessarily.

[Translation done.]

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MEANS

[Means for Solving the Problem]At least one port for drugs conveyance in which it is located a tip and near this tip in an embodiment with this invention, And a catheter for drugs conveyance possessing a catheter shaft provided with at least one lumen for drugs conveyance for supplying drugs to this port for drugs conveyance is proposed. A catheter shaft is further provided with a lumen for guidewires which migrates even to a terminal point from a tip of a catheter shaft, and extends in a catheter shaft. A terminal point is arranged rather than a port for drugs conveyance at the end face side, and an opening for taking out a guidewire from a catheter shaft is formed near the terminal point. Therefore, a catheter shaft is only a wrap in a part of mere guidewire which extends over the outside of the body, and needs neither a long guidewire nor an exchange wire. Preferably, a blockade balloon is provided in order to isolate a drugs transportation area. It is preferred that an additional lumen for inflow is provided. As for a tip of a lumen for inflow, being considered as tapered shape is preferred.

[0010]In other embodiments of this invention, a catheter for expanded type drugs conveyance possessing a catheter shaft provided with a tip part, a tip, and a end face is proposed. An inflation balloon is attached to a tip part of a catheter shaft. The 1st blockade balloon is attached to the tip side position rather than an inflation balloon to a catheter shaft, and the 2nd blockade balloon is attached to the end face side position rather than an inflation balloon to a catheter shaft. In between [at least one] of an inflation balloon and the blockade balloons, a catheter shaft equips a tip part of a catheter shaft with at least one port for drugs conveyance further. At least one lumen for expansion which circulation of a fluid opened for free passage possible to a balloon for expansion is provided. at least one which circulation of a fluid opened for free passage possible to a balloon for a blockade -- swelling -- business -- a lumen is provided. At least one lumen for drugs conveyance which circulation of a fluid opened for free passage possible to a port for drugs conveyance is provided similarly.

[0011]A lumen for guidewires is provided in a tip part of a catheter shaft. The 1st opening that

carries out the opening of the lumen for guidewires to the exterior of a catheter shaft in a tip of a catheter shaft, And it has the 2nd opening that carries out an opening to the exterior of a catheter shaft in a tip part which is a end face side and is substantially located in the tip side rather than a base end of a catheter shaft rather than the 2nd blockade balloon of the catheter shafts. The guidewire can enter in a catheter shaft through the 1st opening, and can come out of a catheter shaft through the 2nd opening. As mentioned above, when the whole catheter shaft has not covered a guidewire, neither a long guidewire nor an exchange wire is required. A problem of a time lag for rearrangement and catheter displacement to a strangulation part after extension is avoided by the ability to carry out that it is also with the same catheter with both extension of a strangulation part, and drugs conveyance.

[0012]In embodiment of a catheter for expanded type drugs conveyance by this invention another again, an inflation balloon attached to a tip part of a catheter shaft has an outer layer and a inner layer. A inner layer forms an interior area near the catheter shaft, and an outer layer and a inner layer form an external area. An outer layer has two or more openings.

Circulation of a fluid is opening the 1st lumen for free passage possible to an outside area, and circulation of a fluid is opening the 2nd lumen for free passage possible to an inner area. The 3rd lumen for accommodating a guidewire is provided in a tip part of a catheter shaft. The 1st opening that carries out the opening of the 3rd lumen to the exterior of a catheter shaft in a tip of a catheter shaft, And it has the 2nd opening that carries out an opening to the exterior of a catheter shaft in a tip part which is a end face side and is substantially located in the tip side rather than a base end of a catheter shaft rather than an inflation balloon of the catheter shafts. The guidewire can enter in a catheter shaft through the 1st opening, and can come out of a catheter shaft through the 2nd opening.

[0013]In another embodiment of this invention, a balloon for drugs conveyance with two or more ports is attached to a tip part of a catheter shaft. A catheter shaft is provided with a lumen provided in a tip part of a catheter shaft in order to accommodate further at least one lumen for conveyance which circulation of a fluid opened for free passage possible to a balloon for drugs conveyance, and a guidewire. The 1st opening that carries out the opening of the lumen for guidewires to the exterior of a catheter shaft in a tip of a catheter shaft, And it has the 2nd opening that carries out an opening to the exterior of a catheter shaft in a tip part which is a end face side and is substantially located in the tip side rather than a base end of a catheter shaft rather than a balloon for drugs conveyance of the catheter shafts. Also in this case, the guidewire can enter in a catheter shaft through the 1st opening, and can come out of a catheter shaft through the 2nd opening. It is preferred that a lumen for inflow is provided. As for a lumen for inflow, it is preferred to have a tapered shape tip.

[0014]In further embodiment of this invention, a drugs transportation means is combined with both sides of space expansion and arrangement of stent which can be balloon expanded in the

same catheter shaft.

[0015]

[Embodyment of the Invention] Drawing 1 is a figure showing the catheter for drugs conveyance by one embodiment of this invention, about the tip part of the catheter, is expanded and is illustrated in the section. Drawing 2 is a sectional view showing the tip part of the catheter shown in drawing 1 along two to 2 line of drawing 1. Drawing 3 is a sectional view in which 90 degrees' rotating and showing the tip part of the catheter shown in drawing 1. Drawing 4 is a sectional view showing the tip part of the catheter shown in drawing 3 along four to 4 line of drawing 3. Drawing 5 is a sectional view showing the base end of the catheter shown in drawing 1 along five to 5 line of drawing 1. Drawing 6 is a top view showing the catheter shown in drawing 3 with the blockade balloon which expanded. Drawing 7 is a figure showing the tip part of a 2nd embodiment of this invention in a flat surface and a section. Drawing 8 is a figure showing the tip part of a 3rd embodiment of this invention in a flat surface and a section. Drawing 9 is a figure showing a 4th embodiment of this invention in a flat surface and a section. Drawing 10 - drawing 13 are the figures showing a 5th embodiment of this invention.

[0016] Drawing 1 - drawing 6 show one embodiment of the catheter 10 for drugs conveyance by this invention. In drawing 1, the tip part of the catheter 10 is expanded and is shown by the section. The catheter 10 is provided with the catheter shaft 12. Preferably, the two blockade balloons 22 and 24 are attached to the tip part of the catheter shaft 12. The 1st lumen 14 that migrates even to the about 24 blockade balloon terminal point 14a from the tip 26 of the catheter shaft 12, and extends is formed so that the guidewire 28 may be received. The opening 30 is formed in the wall of the catheter shaft 12 [near the terminal point 14a]. Preferably, the 1st lumen 14 is arranged near the edge part of the catheter shaft 12. The guidewire 28 can pass along the opening 31 in the tip part 26 of the catheter shaft 12, and can enter into the 1st lumen 14 of the catheter shaft 12, and can come out of the opening 30. Substantially, the opening 30 is located in the tip side of the base end of the catheter 10. The diameter of the 1st lumen can be about 0.022 inch (0.56 mm). At the time of use, the tip part of the guidewire 28 is projected from the tip of the lumen 14, as shown in drawing 1. As for the distance between the tip of a catheter, and the opening 30, it is preferred that it is about 5-25 cm. Although shorter longer or length is possible for the total length of the catheter 10 for drugs conveyance, it can be begun from 120-160 cm. It is not necessary to use too long a wire according to the guidewire 28 being able to come out of the catheter shaft 12 through the opening 30. It is not necessary to use an exchange wire. When removing from the body, a part of mere guidewire which extends over the outside of the body is because it is covered by the catheter 10. Therefore, when the catheter 10 of this invention is inserted into the body or is removed, sufficient allowance for being held in a prescribed position exists in a guidewire. In the catheter 10 by this invention, the guidewire 28 only projects about 75 cm from the body.

[0017]Preferably, the 2nd lumen 16 migrated even to the about 24 blockade balloon terminal point 16a from the tip 26 of the catheter shaft 12 again, and has extended. The diameter of the 2nd lumen can be about 0.013 inch (0.33 mm). Preferably, the wall of the catheter shaft 12 is penetrated and two or more ports 32 are formed so that it may be open for free passage to the 2nd lumen 16. Two or more ports 32 can enable active inflow of the blood which lets a lumen pass so that it may explain further below. It is preferred that the port 32 of circular or an ellipse form a diameter or whose length is 2-20 about 0.003-0.020 inch (0.076-0.51 mm) pieces, respectively is formed. The three openings 32 for inflow are formed in this embodiment. The port 30a which is open for free passage to the 1st lumen 14 for enabling similarly inflow of the blood which lets the 1st lumen 14 pass can be formed between the end face blockade balloon 24 and the opening 30. As for the tip 16b of the 2nd lumen 16, as shown in drawing 1, it is preferred that it is tapered shape. The opening in the tip 16b being able to become difficult to be seen, mistaking to the 1st lumen 14 by this, at the time of use, and inserting the guidewire 28 into the 2nd lumen 16 is prevented. Active inflow of the perfluorochemical known from blood or the former or recombination nature hemoglobin is enabled so that it replaces with such composition, and the lumen 16 may be made to extend covering the whole length of the catheter shaft 12 and this may explain it below.

[0018]Drawing 2 is a sectional view which meets two to 2 line of drawing 1, and shows the 3rd lumen 18 and the 4th lumen 20 to the 1st lumen 14 and the 2nd lumen 16, the port 32, and the pan. The 3rd lumen 18 and the 4th lumen 20 are explained with reference to drawing 3.

[0019]Drawing 3 is a sectional view in which 90 degrees' rotating and showing the tip part of the catheter 10. The graphic display abbreviation of the guidewire 28 is carried out. The 3rd lumen 18 is shown in the figure. This 3rd lumen 18 is for letting the port 34 which penetrates the catheter shaft 12 pass to the blockade balloons 22 and 24, and supplying the fluid for expansion. Preferably, in order to blow up the both sides of the balloons 22 and 24, the single lumen 18 is used. The diameter of the 3rd lumen 18 can be set to about 0.010 (0.25 mm). Similarly, two or more lumina isolated to each balloons 22 and 24 can also be provided.

[0020]The 4th lumen 20 for conveying drugs is illustrated again. Among blockade balloons, at least one port 36 for drugs conveyance penetrates the catheter shaft 12, and it is provided so that it may be open for free passage to the 4th lumen 20. The diameter of the 4th lumen 20 can be set to about 0.010 (0.25 mm). In order to make conveyance of suitable drugs to an expansion part into a positive thing, it is preferred that the port 36 of circular or an ellipse form a diameter or whose length is 2-20 about 0.003-0.020 inch (0.076-0.51 mm) pieces, respectively is formed. In drawing 3, the number of such ports is three. The drugs of arbitrary requests can be conveyed by the 4th lumen 20 to an expansion part. Drawing 4 is a sectional view by four to 4 line of drawing 3 of the catheter shaft 12, and the arrangement situation of two or more lumina which can be set to drawing 3 is shown. The additional lumen for drugs

conveyance can be provided.

[0021]As for the blockade balloons 22 and 24, at the time of drugs conveyance, it is preferred that an expansion part can be isolated. The blockade balloons 22 and 24 maintain drugs near [where it already swelled of the arterial walls] the portion. Thereby, absorption and validity of drugs improve. Drawing 6 is a top view of the catheter 10 of direction of drawing 3, and the blockade balloons 22 and 24 blown up at the time of drugs conveyance just before drugs conveyance are shown. The port 36 for drugs conveyance is also illustrated by the guidewire 28 and pan which have come out of the opening 30 and the opening 30. The opening 32 for inflow is located in the other side of a catheter in this figure.

[0022]It can replace with the integral-type catheter shaft 12 provided with two or more lumina, and the catheter shaft 12 can be provided with two or more tubes pasted up appropriately mutually. In addition, it can expand in drawing 6 and the tip part of the shown catheter shaft 12 can be formed from a material softer than other portions of a shaft. If formed from material with a soft tip part, the operativity which lets a blood circulatory system pass can be raised. On the other hand, pushing nature can be made good if the remaining portion of the shaft is formed from a harder material. These two portions can only be combined with heat adhesion or adhesives which is known in conventional technology. A suitable material is mentioned later. the wire (not shown) of the product made from the product made from stainless steel, or tungsten in order to raise the hardness and pushing nature of the catheter 10 further -- it can provide in the base end of the catheter shaft 12.

[0023]If drawing 1 is referred to again, the two tubes 72 and 74 connected to the catheter shaft 12 are formed in the base end of the catheter 10. One tube is a thing for supply of the fluid for expansion, and is connected to the 3rd lumen 18. The tube of another side is a thing for supply of drugs, and is connected to the 4th lumen 20. The hub 78 is connected with each tube. A syringe can be used, in order to let the tubes 72 and 74 pass and to supply the fluid for expansion to the blockade balloons 22 and 24, and in order to supply the drugs of arbitrary requests. When it is applied for active inflow of the catheter 10 and the 2nd lumen 16 has extended even in the base end of the catheter shaft 12, the 3rd tube (not shown) can be attached to the 2nd lumen 16. When the additional lumen is provided, an additional tube can be attached to the catheter shaft 12. Or Y adapter can be attached. Drawing 5 is a sectional view showing a catheter shaft along five to 5 line of drawing 1, and the 3rd lumen 18 and the 4th lumen 20 are shown.

[0024]As for the outer diameter of the catheter 10 and the blockade balloons 22 and 24 in the state where it became narrower, it is preferred not to exceed about 0.056 inch (1.42 mm).

Thereby, it can be used with 7 or 8 French guiding catheter (7 or 8 French guiding catheter).

[0025]At the place 80, the diameter of the base end 52 of an inside catheter shaft is about expanded even in outer diameter of about 0.140 inch (3.56 mm) so that the tubes 72 and 74

may be received. The tubes 72 and 74 of each other are held with the heat-shrinkable tubing 82. The tubes 72 and 74 are connected to the catheter shaft by heat adhesion or adhesives. [0026]The tip 26 of the 1st lumen 14 is preferably provided with the elastic chip 96 which has a softer material as compared with the material of the catheter shaft 12. When a body tissue is contacted, the chip 96 spreads or it turns at it. Passage of the catheter which passes along a blood circulatory system is made easy by this, and it is useful for prevention of damage to an organization. The chip 96 can be formed from the ultra low density polyethylene 4603 by Dow Chemical Corporation. This material has a melt flow index (ASTM D-1238) of 0.7-0.9g / 10min, and the density (ASTM D-792) of 0.9030-0.9070g/cc in 190 **. The chip 96 can be made into nylon or the polyamide copolymer like PEBA 25D by Elf Atochem Deutschland GmbH. This material The tensile strength of a minimum of 4950 psi (ASTM D-638), It has a minimum of 640% of elongation (ASTM-638), a flexibility factor (ASTM D-790) of a minimum of 2100 psi, a durometer (ASTM D-2240) of 25D**4D, and the melting point (ASTM D-3418) of 142 ** - 153 **. The chip 96 can be connected to the catheter shaft 12 by adhesives or heat adhesion.

[0027]For position observation of the catheter by PTA or the X-ray fluorography at the time of a PTCA operation as the opaque marker 98 is known from the former, for example to the radiation made from gold or tantalum, It is preferred to be provided in the blockade balloon 22 and 24 at the catheter shaft 12, as shown in drawing 1. Such a marker can also be provided in the end face of other arrangement 32, for example, the port of the method of the last.

[0028]The catheter shaft 12 and the blockade balloons 22 and 24 are preferably coated with a charge of a sliding material like silicon, acrylicimide, or hydrophilic polyurethane coating. Thereby, passage of the catheter 10 for drugs conveyance by this invention which passes along a guiding catheter is made easy as known from the former.

[0029]The arbitrary materials for a catheter with a suitable catheter shaft. For example, it can form from linearity low density polyethylene or high density polyethylene, nylon, polyamide, a polyamide copolymer, polyurethane, polypropylene, a polyester copolymer, silicone rubber, or other non-thrombogen formation materials. The product made from stainless steel, or Nitinol (Nitinol) The metal tube made from an available nickel titanium alloy can also be used, for example from Raychem Corporation in a similar manner [of make].

[0030]Suitable linearity low density polyethylene is Dowlex2038 by Dow Chemical Company. This material has a melt flow index (ASTM D-1238) of 0.85-1.15g / 10min, and the density (ASTM D-792) of 0.9330-0.9370g/cc in 190 **. Usable high density polyethylene is LB 8320-00 by Quantum Chemical Corporation. This material has a melt flow index (ASTM D-1238) of 0.20-0.36g / 10min, and the density (D-1505) of a minimum of 0.9566g/cc in 190 **.

[0031]Usable nylon is Nylon 12 like L2101F Vestamed by Huls America Inc. This material has the relative viscosity (ISO 307) of 2.05-2.22, and a maximum of 0.10 water content (ASTM D-4109). Other usable nylon is PEBA-70D by Elf Atochem. This material The tensile strength of a

minimum of 8300 psi (ASTM D-638), It has a minimum of 400% of elongation (ASTM D-638), a flexibility factor (ASTM D-790) of a minimum of 67,000 psi, a durometer (ASTM D-2240) of 69D**4D, and the melting point (ASTM D-3418) of 160 ** - 180 **.

[0032]Usable high density polyethylene is LM6007 by Quantum Chemical Corporation. This material has the following characteristics.

Tensile strength A minimum of 4400 psi (ASTMD-638)

it can set to a burst -- being extended -- % -- a minimum of 600% (ASTM D-638)

D coefficient 68**4.5 of a durometer (ASTM D-2240)

0.070 (REF) at 240 ** and 2160 g

Melt flow index (ASTM D-1238)

Flexibility factor in a room temperature A minimum of 220,000 psi (ASTM D-790, the technique B)

Vicat softening temperature, ** 125 ** (REF)

(ASTM D-1525)

[0033]When it is requested that the tip part of the catheter shaft 12 is softer than other portions of a shaft, usable suitable nylon is PEBA 63D by Elf Atochem. This material The tensile strength of a minimum of 8100 psi (ASTM D-638), It has a minimum of 300% of elongation (ASTMD-638), a flexibility factor (ASTM D-790) of a minimum of 49,000 psi, a durometer (ASTM D-2240) of 63D**4D, and the melting point (ASTM D-3418) of 160 ** - 180 **.

[0034]The catheter shaft 12 provided with the lumen of a desired number can be manufactured by the conventional extrusion process. In order to form the expanding part of the catheter shaft 12, a vamp extrusion process can be used as known in conventional technology. It can replace with the integral-type catheter shaft 12 with a lumen, and two or more individual tubes connected mutually can be used.

[0035]The elastic chip 96 can be attached to a catheter shaft by carrying out heat adhesion in a prescribed position by arranging the small tube of the charge of a chipped material on the tip of the catheter shaft 12. Similarly, adhesives can be used. The catheter shaft 12 will increase the charge of a tube material. In order to maintain the outer diameter of the catheter shaft 12 after arrangement of the tube of the charge of a chipped material smaller than about 0.056 inch (1.42 mm), In advance of attachment of the charge of a chipped material, only a suitable quantity "being able to shut (necked-down)" the tip part of a catheter shaft. [make able to decrease it or] In order to attach an elastic chip by heat adhesion, maintaining the lumina 14 and 16 to an opening state, an axis is inserted into each lumen. The tube of the charge of a chipped material can extend even to the field to which the tip blockade balloon 22 of the catheter shafts 12 is attached. In this case, all or some of balloons 22 can attach to the charge of a chipped material.

[0036]At the time of heat adhesion of the charge of a chipped material, the tip part of the 3rd

lumen 18 and the 4th lumen 20 is blockaded. When it is required to blockade more portions of one of lumina, the small solid tube made from the same material as the catheter shaft 12 is inserted into the end face of the lumen, and heat adhesion is carried out after that in a prescribed position. Adhesives can be used similarly. The thing large more slightly than the diameter of said lumen of the outer diameter of a tube is preferred. An axis maintains other lumina to an opened condition. When the 3rd lumen 18 is not blockaded at the time of attachment of the elastic chip 96, it can blockade like the 4th lumen.

[0037]The seal of the base end of the 1st lumen 14 and the 2nd lumen 16 can be carried out similarly.

[0038]The blockade balloons 22 and 24 Nylon, polyamide, a polyamide copolymer, It can form from polyethylene, polyethylene terephthalate, a polyester elastomer, polyurethane, Kapton (Kraton), silicone, latex, or other arbitrary flexible non-thrombogen formation materials.

Although the blockade balloons 22 and 24 do not blow up a blood vessel wall when it swells, they carry out the seal of the blood vessel wall. A balloon can be used as the balloon by which could consider it as the tube which swells by expansion, or blow molding was carried out.

When balloon material has conformity to the catheter shaft 12, the blockade balloons 22 and 24 can be attached by heat adhesion art including laser adhesion. The device and method for carrying out laser adhesion of the balloon on a catheter are indicated by U.S. Pat. No.

5,267,959. This literature is incorporated here for reference. Adhesives can be used similarly.

Nylon usable as the blockade balloons 22 and 24 is L25G Grilamid by EMS-Chemie AG. This material The melting point of 178 **, the density of 1.01 kg/dm³ (DIN 53479), It has the tensile strength (DIN 53455) of 40N/[mm]², the elongation (DIN 53455) in 10% of burst, and the Shore (Shore)D hardness (DIN 53505) of 72.

[0039]After expansion is attained by the usual method, the catheter for drugs conveyance by a 1st embodiment of this invention can be used even for the treatment part by the PTA method or the PTCA method in order to convey drugs. An expansion catheter consists of a quick exchange format which is indicated by Mr. Bonzel's U.S. Pat. No. 4,762,129 preferably, for example. This literature is incorporated here for reference. Such a catheter is removed first. After that, the catheter 10 for drugs conveyance of this invention is introduced in a blood circulatory system, and is carried forward even to an expansion part via a guiding catheter along with the same guidewire that showed said expansion catheter even to the strangulation part. An exchange wire is not required at all and the guidewire needs to project only about 75 cm from the body. The tip of the 1st lumen 14 of the catheter 10 is inserted into a guidewire like the guidewire 28 shown in drawing 1. When a catheter advances along with a guidewire, the guidewire has come out of the opening 30 of the catheter 10. The catheter 10 continues being conveyed along with the portion located in the 1st lumen 14 of the guidewires, when moving forward even to an expansion part.

[0040]The progress condition of the catheter 10 is pursued by X-ray fluorography. When it arrives at an expansion part, it swells through the 3rd lumen 18 until the blockade balloons 22 and 24 carry out the seal of the arterial wall in contact with an arterial wall. When the openings 32 and 30a for inflow exist, it flows through the 2nd lumen 16 and the 1st lumen 14, and flows out of the tip part of the catheter 10, respectively. When it is constituted so that the catheter 10 can perform active inflow (.) Namely, when the 2nd lumen 16 has extended covering the whole length of the catheter shaft 12. Blood or a fault fluorine compound like Fluosol (registered trademark), and recombination nature hemoglobin can be poured in by a syringe via the tube 76 as known in conventional technology.

[0041]An anti-thrombolysis agent, an anti-growth agent, or drugs arbitrary type [other] can be poured in by a syringe here through the tube 72, the 4th lumen 20, and also the port 36 for drugs conveyance. One effective gestalt of drugs is the dexamethasone made to stick to the polylactic acid / polyglycolic acid particles of a diameter smaller than 100 microns substantially. Such particles stick to an arterial wall, or can penetrate an arterial wall. A particle surface can be processed with cell adsorptivity protein, in order to heighten the adsorption power of the particles to an arterial wall. Peptide based on usable arginine glycine aspartic acid is Peptite 2000 (registered trademark) by Telios Pharmaceuticals and Inc.

[0042]After continuing for desired time (typically about 20 seconds - 3 minutes) and applying drugs by a desired pressure, a blockade balloon is ***** (ed) and the catheter 10 for drugs conveyance is drawn out promptly and easily from a blood vessel.

[0043]Drawing 7 is a figure showing the tip part of a 2nd embodiment of this invention in a flat surface and a section, and the catheter 100 which can perform both extension and drugs conveyance is shown. The catheter 100 is provided with the catheter shaft 110 which has the 1st lumen 112, the 2nd lumen 114, the 3rd lumen 116, and the 4th lumen 118. The inflation balloon 120 and the two blockade balloons 122 and 124 are attached to the catheter shaft 110. The free passage of the 1st lumen 112 and a fluid of the inflation balloon 120 is enabled through the opening 126. The free passage of the 4th lumen 118 and a fluid of both blockade balloons is similarly enabled through the opening 128. The wall of the catheter shaft 110 is penetrated in the 2nd lumen 114, the port 130 is established in it, it can let this port 130 pass, and medication to an expansion part can be performed. The additional lumen for drugs conveyance can be provided like the above. The additional lumen can provide a fluid to the blockade balloons 122 and 124 as opposed to the inflation balloon 120 similarly. The wall of the catheter shaft 110 is penetrated to the 3rd lumen 116, and the opening 132 is formed in it. The 3rd lumen 116 that penetrated the opening 133 in the tip 134 of the catheter 100, and has extended has accommodated the guidewire 136 which exists in this lumen 116 through the opening 132. an additional lumen (not shown) -- it may provide for active or passive inflow. The tip of such a lumen for inflow is preferably made into tapered shape as mentioned above. The

above slide coating is applied to the inflation balloon 120 and the remaining portion of the catheter 100. As mentioned above, it can replace with the integral-type catheter shaft which has two or more lumina, and the catheter shaft 110 can consist of two or more tubes combined appropriately mutually.

[0044]The inflation balloon 120 can be made into the thing of the suitable arbitrary types for the PTA method and the PTCA method, and size. For example, the balloon 120 can be formed from polyethylene, polyethylene terephthalate, nylon, polyamide, a polyamide copolymer, polyurethane, or other arbitrary materials suitable as an inflation balloon. the balloon 120 -- adaptability and non-adaptability -- or -- half-- suppose that it is flexible. The inflation balloon 120 can be attached to the catheter shaft 110 with the heat adhesion including laser adhesion or ultrasonic bonding or adhesives as known in conventional technology. As for the balloon 120, it is preferred that it is the same material as the catheter shaft 110, or is a conformable material so that heat adhesion may be possible.

[0045]Low density polyethylene usable as the inflation balloon 120 is P.E.1031 by RexeneCorporation. In 190**0.2 **, this material The melt flow index of 0.4-1.4g / 10min (ASTM D-1238), It has the density (ASTM D-1505) of 0.93**0.02g/cc, and the melting point (ASTM D-3417, D-3418) of 104-140 **. Usable linearity low density polyethylene is Dowlex2247A LLPDE by Dow Chemical Corporation. In 190 **/2.16 kg, this material The melt index of 2.0-2.6g / 10min (ASTM D-1238), It has the density (ASTM D-1505) of 0.9150-0.9190g/cc, and the melting point (D-3417, D-3418 (REF)) of 122-125 **.

[0046]The material mentioned above in relation to a 1st embodiment is suitable for other corresponding members in this embodiment. The radiation opaque marker 138 is established under the blockade balloons 122 and 124 under the inflation balloon 120 like a 1st embodiment again at the catheter shaft 110. The structure of the end face of the catheter 100 is intrinsically [as the end face of the catheter 10 shown in drawing 1] the same. However, only the point that the 3rd tube for supplying the fluid for expansion to the inflation balloon 120 through the 1st lumen 112 is attached is different from the end face of the catheter shaft 110. Y adapter can be used again as known in conventional technology.

[0047]At the time of use, the catheter 100 of this embodiment is inserted in a guidewire like the guidewire 136 already advanced even to the strangulation part by the guiding catheter as known in conventional technology. It invaded through the opening 134 in the catheter 100, and has come out from the 3rd lumen 116 through the opening 132. As mentioned above, when some catheters 100 are carrying out friction engagement with the guidewire, while being able to follow a catheter to a strangulation part easily and promptly, the guidewire to be used is short and ends. When arranged properly, the inflation balloon 120 can swell by the conventional method, in order to open a strangulation part. Then, it is made to become narrower about the inflation balloon 120, and the blockade balloons 122 and 124 can be blown

up as mentioned above. The drugs of arbitrary requests can be supplied through the 2nd lumen 114 after that. By the ability to perform both extension and drugs conveyance as it is also with the same catheter, in this embodiment, time required to draw out the catheter for expansion and insert the catheter for drugs conveyance of a different body further can be saved, and operation time can be shortened. In addition, in this embodiment, the problem of the exact rearrangement to the expansion part for the optimal location and allocation of the catheter for drugs conveyance can be eased.

[0048]In a 3rd embodiment of this invention, both extension of a strangulation part and drugs conveyance to an extended part can be performed as, as for the catheter 200, the same inflation balloon is also. Drawing 8 is a figure showing the tip part of such a catheter 200 in a flat surface and a section, and the state where the inflation balloon expanded is shown. The catheter 200 is provided with the catheter shaft 210, the 1st lumen 212, the 2nd lumen 214, and the 3rd lumen 216. The 2nd lumen 214 has accommodated the guidewire 218 through the opening 219. In order to form the exit of the guidewire 218, the catheter shaft 210 is penetrated in the 2nd lumen 214, and the opening 217 is formed in it. It can replace with the integral-type catheter shaft which has two or more lumina, and the catheter shaft 210 can consist of two or more tubes combined appropriately mutually.

[0049]The balloon part of the catheter 200 is provided with the outside balloon 220 and the inner balloon 230. The 2nd lumen 214 inserted in the inside of the inner balloon 230, and has extended. The tip of the outside balloon 220 is pasted up with heat or adhesives to the tip of the inner balloon 230. On the other hand, at the place 240, the tip of the inner balloon 230 is pasted up with heat or adhesives to the outside surface of the 2nd lumen 214. Both the end faces of the outside balloon 220 and the inner balloon 230, To the catheter shaft 210, it is in the state in which the middle field of an outside balloon and an inner balloon is carrying out fluid communicating to the 1st lumen 212, and has pasted up with heat or adhesives in the state where the inside of the inner balloon 230 is carrying out fluid communicating to the 3rd lumen 216. The fluid for expansion is supplied through the 3rd lumen 216, and drugs are supplied through the 1st lumen 212. In order that two or more micropores 280 may emit drugs from a balloon, the wall of the outside balloon 220 is penetrated and it is formed. Such a hole can be 0.01 micron - 0.1 mm. When the outer layer of the balloon 220 is provided with polyethylene terephthalate, nylon, or biaxial orientation plastic material like a polyester elastomer, the micropore 280 can be formed using high-precision laser.

[0050]At the time of use, the guidewire 218 is advanced to the fault part with which it should deal via a guide catheter by the conventional method. The tip of the 2nd lumen 214 is attached over the base end of the guidewire 218. The guidewire has come out from the catheter 200 through the opening 217 like both the above-mentioned embodiments. The catheter 200 continues advance along with the portion in the 2nd lumen 214 of the guidewires until it arrives

at the fault part where it should deal with a balloon part. In drawing 8, the inner layer 230 and the outer layer 220 of the balloon part are illustrated by the expanding state, however when these layers move forward to a strangulation part, they are in the state where it stuck to the outside surface of the lumen 214.

[0051]If the tip part of the catheter 200 is appropriately arranged using the radiation opaque marker band 242, selected drugs will let the 1st lumen 212 pass, and will be introduced into the staging area of outside balloon 220 and the inside balloon 230. Although pouring of drugs brings about some extension of the outside balloon 220, typically, the pressure that drugs are poured in is smaller than the pressure that the quantity of drugs will be substantially emitted from the micropore 280. In order to perform both drugs conveyance and extension simultaneously next, the fluid for expansion lets the 3rd lumen 216 pass, and is poured in inside the inner balloon 230. If a pressure increases and 7-8 atmospheres will be reached typically, the inner layer 230 of a balloon will swell even to a predetermined maximum diameter. And by swelling in this way, to the fault part with which it deals that it is also with special drugs, it can let the port 280 pass and drugs can be sprinkled effectively. While the pressure which acts to a fault part is brought about again and drugs apply by expansion of the inner balloon 230, forcing to a blood vessel wall can be performed.

[0052]Use of the balloon for conveyance of the drugs to the expansion part by the catheter for drugs conveyance of this invention is shown in a 4th embodiment of drawing 9. The catheter 300 is provided with the balloon 312 for drugs conveyance attached by heat or adhesives to the catheter shaft 310 as mentioned above. The balloon 312 is shown by the expanding state in drawing 9. Two or more ports 314 for drugs conveyance are formed over the balloon 312. The balloon 312 lets the port 318 which penetrates the wall of the catheter shaft 310 pass, and is carrying out fluid communicating to the lumen 316 for drugs conveyance. The additional lumen for drugs conveyance can be provided again. The lumen 320 for guidewires penetrates the tip 322, and is provided in the tip part of the catheter shaft 310. The termination of the lumen 320 for guidewires is carried out to the end face side of the balloon 312 for drugs conveyance of the tip parts of the catheter shaft 310. The opening 324 which is open for free passage to the lumen 320 for guidewires is formed in the wall of the catheter shaft 310. The guidewire 326 can be inserted through the opening 328 in the tip 322 of the catheter shaft 310, and can be taken out through the opening 324.

[0053]It is preferred to form the lumen 330 for inflow in which the tapered shape end 330a was formed. As mentioned above, this lumen can extend covering the whole length of the catheter shaft 310 so that active inflow may be enabled. It can replace with this and the termination of this lumen can be carried out to the end face side of the balloon 312 for drugs conveyance. In that case, in order to enable active inflow, like a 1st embodiment, the wall of the catheter shaft 310 can be penetrated and two or more openings (not shown) can be provided. It can replace

with the integral-type catheter shaft provided with two or more lumina, and the catheter shaft 310 can consist of two or more tubes pasted up appropriately mutually.

[0054]A 5th embodiment of the invention in this application combines a space expansion function and a local drugs carrying function with the balloon extension type stent. The non-expanding state and the expanding state are shown in drawing 10, 11 and drawing 12, and 13, respectively. The catheter 400 is provided with the object for double-wall type expansion and the balloon 412 for drugs conveyance which it was welded or were pasted up on the catheter shaft 401 like ****, the 1st lumen 405, the 2nd lumen 406, and the 3rd lumen 407. The 2nd lumen 406 has received the guidewire 418 through the opening 419. To the 2nd lumen 406, the catheter shaft 401 is penetrated and the opening 417 is formed. This opening 417 can make the exit for the guidewire 418. It can replace with the integral-type catheter shaft in which two or more lumina are provided, and the catheter shaft 401 can also consist of two or more tubes pasted up mutually again.

[0055]The double-wall balloon 412 is the same as the double-wall balloon in a 3rd embodiment of this invention. The stent 440 which can be balloon expanded is attached to the double-wall balloon. Means of attachment can be performed by other arbitrary methods of demounting the stent from a double-wall balloon at the time of engagement, and balloon expansion and stent deployment.

[0056]At the time of use, the guidewire 418 is advanced to the fault part with which it should deal via a guide catheter by the conventional method. The tip 419 of the 2nd lumen 406 is attached over the base end of the guidewire 418. The guidewire has come out from the catheter 400 through the opening 417 like both the above-mentioned embodiments. The catheter 400 continues advance along with the portion in the 2nd lumen 406 of the guidewires until it arrives at the fault part where it should deal with a balloon part. In drawing 10 - drawing 13, the inner layer 430 and the outer layer 420 of the balloon part are illustrated by the expanding state, however when these layers move forward to a strangulation part, they are in the state where it stuck to the outside surface of the lumen 419.

[0057]If the tip part of the catheter 400 is appropriately arranged using the radiation opaque marker band 442, selected drugs will let the 3rd lumen 407 pass, and will be introduced into the staging area of outside balloon 430 and the inside balloon 420. Although pouring of drugs brings about some extension of the outside balloon 430, typically, the pressure that drugs are poured in is smaller than the pressure that the quantity of drugs will be substantially emitted from the micropore 428. In order to perform drugs conveyance, extension of strangulation, and arrangement of the stent simultaneously next, the fluid for expansion lets the 1st lumen 405 pass, and is poured in inside [421] an inner balloon. If a pressure increases and 7-8 atmospheres will be reached typically, the inner layer 420 of a balloon will swell even to a predetermined maximum diameter. And while being able to sprinkle drugs effectively to the

fault part with which it deals that it is also with special drugs by swelling in this way, the stent is expanded and the stent can be pushed to a blood vessel wall. Drugs are emitted from the hole of an outside balloon and permeate through the lattice of the stent.

[0058]In the catheter for drugs conveyance and the catheter for expanded type drugs conveyance by this invention, advance and drawing out of a quick and easy catheter are possible, and, therefore, the time which an operation takes can be shortened. A required staff and device can be omitted and operation cost can be reduced.

[0059]In the above, although the desirable embodiment of this invention has been described, the above-mentioned embodiment does not restrict the range of this invention, and the range of this invention is defined by the claim.

[Translation done.]

*** NOTICES ***

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- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.**** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1]It is a figure showing the catheter for drugs conveyance by one embodiment of this invention, and about the tip part of the catheter, it expands and is illustrated in the section.

[Drawing 2]It is a sectional view showing the tip part of the catheter shown in drawing 1 along two to 2 line of drawing 1.

[Drawing 3]It is a sectional view in which 90 degrees' rotating and showing the tip part of the catheter shown in drawing 1.

[Drawing 4]It is a sectional view showing the tip part of the catheter shown in drawing 3 along four to 4 line of drawing 3.

[Drawing 5]It is a sectional view showing the base end of the catheter shown in drawing 1 along five to 5 line of drawing 1.

[Drawing 6]It is a top view showing the catheter shown in drawing 3 with the blockade balloon which expanded.

[Drawing 7]It is a figure showing the tip part of a 2nd embodiment of this invention in a flat surface and a section.

[Drawing 8]It is a figure showing the tip part of a 3rd embodiment of this invention in a flat surface and a section.

[Drawing 9]It is a figure showing a 4th embodiment of this invention in a flat surface and a section.

[Drawing 10]It is a figure showing a 5th embodiment of this invention.

[Drawing 11]It is a figure showing a 5th embodiment of this invention.

[Drawing 12]It is a figure showing a 5th embodiment of this invention.

[Drawing 13]It is a figure showing a 5th embodiment of this invention.

[Description of Notations]

400 Catheter

401 Catheter shaft
405 Lumen
406 Lumen
407 Lumen
412 Balloon
417 The 2nd opening
418 Guidewire
419 Tip
420 Inner layer
428 (For drugs discharge) Opening
430 Outer layer
440 Stent

[Translation done.]

